



Clinical Guidance for COVID-19 Vaccination

Version 51 13/12/2023

This document has been created and updated by the HSE National Immunisation Office

Date of revision	13/12/2023
Update	<p>Updates have been made to the following sections of this Clinical Guidance:</p> <ul style="list-style-type: none"> Table 1. NIAC recommendations for COVID-19 vaccines by age and immune status November 2023: available vaccines updated Section 3. COVID-19 vaccines. Vaccines no longer available for use in the COVID-19 Immunisation Programme in Ireland. Table 3: Vaccines used in the COVID-19 Immunisation Programme: available vaccines updated Section 7. Protein Sub-Unit Vaccine: Nuvaxovid® XBB.1.5(NEW) Section 8. Contraindications and precautions to COVID-19 vaccines Section 8.1 mRNA vaccines - Contraindications to mRNA vaccines Section 8.2 Protein sub-unit vaccine Nuvaxovid® XBB.1.5 (NEW) 9.1 Pregnancy – Booster vaccination in pregnancy with Nuvaxovid® XBB.1.5 (NEW) Section 10. Booster COVID-19 Vaccines Section 10. Booster vaccination with Nuvaxovid® XBB.1.5 (NEW) Table 7. Adapted Vaccine Summary Section 10. Booster vaccination in pregnancy Section 12: Adverse reactions Table 8: Adverse reactions of COVID-19 vaccines from clinical trials and post authorisation experience 12.3 Adverse events following Nuvaxovid® (Novavax) and unknown frequency of cases of Myocarditis and Pericarditis <p>Removed Sections:</p> <ul style="list-style-type: none"> Previous Section 7. Protein Sub-Unit Vaccines: Nuvaxovid® (Novavax) Previous Section 8. Protein Sub-Unit Vaccines: VidPrevtyn Beta® Previous Section 9.2 Protein sub-unit vaccines Nuvaxovid® Previous Section 9.3 VidPrevtyn Beta Previous Section 10.1 Pregnancy - Vaccination in pregnancy with Nuvaxovid® Previous 10.1 Pregnancy - VidPrevtyn Beta® is not recommended for vaccination in pregnancy as routine Previous section 10.11 Contraindication to mRNA vaccines Previous section 11. Booster COVID-19 vaccines - Nuvaxovid

Contents

1. Introduction	5
2. Vaccine recommendations	6
2.1 Medical conditions at very high risk and high-risk of severe COVID-19 disease	8
3. COVID-19 Vaccines	10
4. Infection Prevention and Control for the administration of COVID-19 Vaccines	11
5. Vaccine details, storage and instructions for preparation and administration	12
6. Adapted COVID-19 mRNA Vaccines	13
6.1 Comirnaty® Original/Omicron BA.4-5 30 micrograms (0.3ml)	13
6.2 Comirnaty® Omicron XBB.1.5 30 micrograms (0.3ml)	17
7. Protein Sub-Unit Vaccine: Nuvaxovid® XBB.1.5	19
8. Contraindications and precautions to COVID-19 vaccines	23
8.1 mRNA Vaccines	23
8.2 Protein sub-unit vaccine Nuvaxovid® XBB.1.5	24
8.3 Vaccination after COVID-19 (primary vaccination course)	25
9. Clinical considerations for COVID-19 vaccines	26
9.1 Pregnancy	26
9.2 Breastfeeding	27
9.3 Fertility	27
9.4 Individuals with a bleeding disorder	28
9.5 Individuals taking anticoagulants	28
9.6 Technique for IM injections in persons with bleeding disorders or on anticoagulants	28
9.7 Co-administration of COVID-19 vaccines with other inactivated or live vaccines for those aged 12 years and over	28
9.8 Immunosuppression due to disease or treatment	29
9.9 Extended primary course for those with immunosuppression due to disease or treatment: mRNA vaccines	29
9.10 Vaccination with the additional dose after breakthrough infection	29
9.11 People being treated with chemotherapy for cancer	30
9.12 Heterologous vaccination	30
10. Booster COVID-19 Vaccines	31
11. Post Vaccination	36
11.1 Recording vaccination	36
11.2 Observation period	36
12. Adverse Reactions	37
12.1 Adverse reactions of COVID-19 vaccines	37
12.2 Adverse events following Comirnaty® (Pfizer/BioNTech) and Spikevax® (Moderna) and very rare cases of Myocarditis and Pericarditis	38
12.3 Adverse events following Nuvaxovid® (Novavax) and unknown frequency of cases of Myocarditis and Pericarditis	39
12.4 Reporting adverse reactions	39
12.5 Reporting of incidents during the vaccination session to HSE	40
13. Guidance for vaccination of those who are contacts of a case of COVID-19	41
14. Vaccination of children aged 5-11 years	42
14.1 NIAC recommendation	43
14.2 Formulations for booster vaccination of those aged 5-11 years	43
14.3 Vaccine storage for Comirnaty® formulations for those aged 5-11 years	44
14.4 Vaccine dose (for both Comirnaty® Omicron XBB.1.5 and Comirnaty® Original/Omicron BA.4-5 for children aged 5-11 years)	46
14.5 Interval between doses (of Comirnaty® Original/Omicron BA.4-5 10 micrograms (0.2ml) when used for primary vaccination of children aged 5-11 years)	46
14.6 Infection prevention and control	47
14.7 Vaccine, Preparation and Dilution	48
14.8 Vaccine Administration of Comirnaty® for 5-11 years	50
14.9 Method of IM Vaccine Administration	51
14.10 Positioning for vaccination	51
14.11 Techniques for vaccinating children	52

14.12 Contraindications and precautions to COVID-19 vaccination in children aged 5-11 years for Comirnaty® Original/Omicron BA.4-5 10 micrograms (0.2ml) and for Comirnaty® Omicron XBB.1.5 10 micrograms (0.2ml)	53
14.13 Post-vaccination Procedures	54
14.14 Adverse Events	54
14.15 Clinical considerations	55
15. Vaccination of Children Aged 6 months to 4 years:	58
15.1 NIAC Recommendation.....	58
15.2 Vaccine storage	59
15.3 Vaccine dose	60
15.4 Prior to vaccination	61
15.5 Consumables needed.....	61
15.6 Infection prevention and control	61
15.7 Vaccine Administration.....	65
15.8 Contraindications and precautions to COVID-19 vaccination in children aged 6 months to 4 years	68
15.9 Post-vaccination Procedures	68
15.10 Adverse Events	69
15.11 Clinical Considerations	69
Useful links	72
APPENDIX A: INTRAMUSCULAR INJECTION TECHNIQUE	73
APPENDIX B: SOP	75
APPENDIX C: ADVICE FROM THE NATIONAL IMMUNISATION ADVISORY COMMITTEE REGARDING FEVER AFTER COVID-19 VACCINATION	91

This guidance is intended for vaccinators administering COVID-19 vaccines. Vaccinators should be trained and competent in immunisation practice.

Vaccinators should have undergone training in the administration of COVID-19 vaccine(s), recognition and management of anaphylaxis, and basic life support and intramuscular injection technique. They should also be familiar with the anaphylaxis protocol outlined in the Immunisation Guidelines for Ireland (see useful links section).

In some circumstances, advice in these guidelines may differ from that in the Summary of Product Characteristics (SmPC) of the vaccines. When this occurs, the recommendations in these guidelines, which are based on current expert advice from the National Immunisation Advisory Committee should be followed.

1. Introduction

The objective of the vaccination programme for SARS-CoV-2 is to ensure equitable access to a safe and effective vaccine with the goals of limiting mortality and morbidity from COVID-19, protecting healthcare capacity and enabling social and economic activity.

Purpose of the document

This document has been prepared as a means of providing clinical guidance to all clinicians implementing the COVID-19 vaccination programme.

Indemnity for vaccinators

Claims management in relation to claims and litigation initiated in connection with COVID-19 vaccination is to be delegated to the State Claims Agency by means of Government Order.

Registered medical practitioners (including GPs), nurses, pharmacists, physiotherapists, dentists, dental hygienists, optometrists, radiographers and radiation therapists, paramedics, advanced paramedics, emergency medical technicians and relevant healthcare students (as per the Statutory Instruments for the administration of COVID-19 vaccines), in receipt of relevant training with regard to administration of the vaccines, who are administering vaccines on the direction of, or on behalf of, the Health Service Executive (HSE) will be indemnified with regard to any adverse product liability- related events arising from their administration of the vaccine. Vaccinators working in GP surgeries and retail pharmacies however, will not be indemnified in respect of malpractice events occurring during the administration of the vaccine. Such malpractice events will be indemnified by their professional insurers.

2. Vaccine recommendations

Recommendations for primary and booster vaccination are summarised in the table below.

Table 1: NIAC recommendations for COVID-19 vaccines by age and immune status November 2023

Age	Primary schedule	1 st Booster dose interval ¹	2023 Recommendations		Available COVID-19 vaccines
			Interdose interval ²	Further booster doses	
70 and older	Recommended: Two doses with interval of four weeks between doses ³	Recommended: Four months	Six months	Irrespective of number of prior booster doses: A booster vaccine is recommended in autumn.	For those aged 30 and older <i>As primary and booster:</i> Comirnaty Original/Omicron BA.4-5 30 micrograms (0.3ml) <i>As booster only:</i> Comirnaty Omicron XBB.1.5 30 micrograms (0.3ml) Nuvaxovid XBB.1.5 5mcg (0.5ml)
50-69 years	Recommended: Two doses with interval of four weeks between doses ³	Recommended: Four months	Six months	Irrespective of the number of prior booster doses: A booster vaccine is recommended for all in autumn.	
30-49 years	Recommended: Two doses with interval of four weeks between doses ³	Recommended: Four months	Nine months ⁴	For those healthy aged 18-49 years who have availed of the offer of a second booster dose additional booster vaccines are not routinely recommended ⁵	
18-29 years	Recommended: Two doses with interval of eight weeks between doses ³	Recommended: Four months	Nine months ⁴	A booster vaccine is recommended in autumn for: <ul style="list-style-type: none"> those with immunocompromise associated with a suboptimal response to vaccination those with medical conditions associated with a higher risk of COVID-19 hospitalisation, severe disease or death⁶ Access to an autumn booster vaccine should be available for those who, following discussion of their reasons with a health care provider (e.g., GP, pharmacist or vaccination centre), request vaccination.	For those aged 18-29 <i>As primary and booster:</i> Comirnaty Original/Omicron BA.4-5 30 micrograms (0.3ml) <i>As booster only:</i> Comirnaty Omicron XBB.1.5 30 micrograms (0.3ml) Nuvaxovid XBB.1.5 5mcg (0.5ml)
12-17 years	Recommended: Two doses with interval of eight weeks between doses ³	Available to all Four months Recommended for those with immunocompromise four months	Nine months ⁴	Additional booster vaccines are not routinely recommended. Irrespective of the number of prior booster doses: A booster vaccine is recommended in autumn for: <ul style="list-style-type: none"> those with immunocompromise associated with a suboptimal response to vaccination those with medical conditions associated with a higher risk of COVID-19 	For those aged 12-17 <i>As primary and booster:</i> Comirnaty Original/Omicron BA.4-5 30 micrograms (0.3ml) <i>As booster only:</i> Comirnaty Omicron XBB.1.5 30 micrograms (0.3ml) Nuvaxovid XBB.1.5 5mcg (0.5ml)

				hospitalisation, severe disease or death ⁶	
5-11 years	Recommended for those with underlying conditions. ⁶ Available to others Two doses with interval of eight weeks between doses ³	Recommended for those with immunocompromise Four months	Nine months ⁴	Booster vaccines are not routinely recommended. Irrespective of the number of prior booster doses: A booster vaccine is recommended in autumn for: <ul style="list-style-type: none"> those with immunocompromise associated with a suboptimal response to vaccination those with medical conditions associated with a higher risk of COVID-19 hospitalisation, severe disease or death.⁶ 	For those age 5-11 <i>As primary and booster:</i> Comirnaty Original/Omicron BA.4-5 10 micrograms (0.2ml) <i>As booster only:</i> Comirnaty Omicron XBB.1.5 10 micrograms (0.2ml)
6 months-4 years	Recommended for those with underlying conditions. Available to others Three doses, with three weeks interval between dose one and two, and eight weeks between dose two and three	Not recommended	Not applicable	Booster vaccines are not recommended .	For those aged 6 months-4 years <i>As primary:</i> Comirnaty 3 micrograms (0.2ml)
Immunocompromised aged 5 years and older	Recommended Three doses with four weeks interval between dose one and two, and eight weeks between dose two and three ⁸	Recommended: Four months	Six months	Irrespective of the number of prior booster doses: <ul style="list-style-type: none"> a booster vaccine is recommended in autumn 	<i>Age related as listed above</i>
Health Care Workers	Recommended <i>Age related as listed above</i>	Recommended Four months	<i>Age related as listed above</i>	Irrespective of the number of prior booster doses: a booster vaccine is recommended for all in autumn	<i>Age related as listed above</i>
Pregnancy	Recommended <i>Age related as listed above</i>	Recommended Four months	Six months	For pregnant adolescents and adults a COVID-19 booster vaccine once ⁷ in pregnancy is recommended if it is more than six months since their previous COVID-19 vaccine or infection. <ul style="list-style-type: none"> COVID-19 vaccine can be given at any stage in pregnancy the booster is ideally given between 20-34 weeks' gestation If it is more than 12 months since their previous COVID-19 vaccine or infection administration earlier in pregnancy should be considered.	<i>Age related as listed above</i>

¹ Interval since completion of primary course or SARS-CoV-2 infection following the primary course, and first booster dose

² Interval since last booster dose or SARS-CoV-2 infection, in exceptional circumstances a minimum interval of three months may be used

³ A minimum interval of three weeks may be used if there is urgency to achieve protection

⁴ The recommended interdose interval for those with immunocompromise aged 5 years and older is six months irrespective of age

⁵ For those aged 18-49 years who have not had a second booster, it may be given after a nine month interval

⁶ Medical conditions associated with a higher risk of COVID-19 hospitalisation, severe disease or death are outlined in Table 5a.2

⁷ For those who are pregnant and are immunocompromised, a second booster dose within the same pregnancy may be considered if six months has elapsed since their last booster dose or SARS-CoV-2 infection

⁸ A minimal interval of 4 four weeks between the second and third dose may be used if there is urgency to achieve protection

OF NOTE: COVID-19 booster vaccines as outlined above for the Autumn 2023 campaign may be given irrespective of the number of previous booster doses or types of COVID-19 vaccines received as follows:

- for those aged 50 years and older an interval of **6 months** is recommended following any previous COVID-19 vaccine dose or infection
- for those aged 5 and older with immunocompromise associated with a suboptimal response to vaccination, an interval of **6 months** is recommended following any previous COVID-19 vaccine dose or infection
- for those aged less than 50 years an interval of **9 months** is recommended following any previous COVID-19 vaccine dose or infection
- a minimum interval of **3 months** is permissible in exceptional circumstances e.g., heightened epidemiologic risk or for operational reasons.

2.1 Medical conditions at very high risk and high-risk of severe COVID-19 disease

Conditions at high risk or very high risk of severe COVID-19 disease are detailed in Table 2 on page 9.

Those with conditions in the **blue shaded** areas are immunocompromising conditions that may be associated with a suboptimal response to vaccines. People with these conditions at the time of vaccination require an additional dose of vaccine for their primary vaccination course (see [Section 9.9](#)) as well as a number of booster vaccine doses as outlined in Table 1.

Table 2. Conditions or treatments associated with very high or high risk of severe COVID-19 disease

Medical condition	Very high risk	High risk
Cancer	Receiving or within 6 weeks of receiving systemic cytotoxic chemotherapy, targeted therapy, monoclonal antibodies or immunotherapies Receiving treatment or pending treatment for a haematological cancer Undergoing or within 6 weeks of surgery or radical radiotherapy for lung or head and neck cancer Advanced/ metastatic cancer	Haematological ¹ - within 5 years of treatment Non haematological cancer within 1 year following immunomodulating treatment All other cancers being treated (excluding hormonal treatment)
Chronic heart and vascular disease		e.g. heart failure, hypertensive cardiac disease
Chronic kidney disease	On dialysis, or eGFR <15 ml/min	With eGFR <30ml/min
Chronic liver disease		e.g. cirrhosis or fibrosis
Chronic neurological disease or condition	With evolving respiratory failure requiring non- invasive ventilation e.g. motor neurone disease, spinal muscular atrophy	Significantly compromised respiratory function and/or the ability to clear secretions e.g. Parkinson's disease, cerebral palsy
Chronic respiratory disease	Severe e.g., severe cystic fibrosis, severe COPD, severe pulmonary fibrosis	Other conditions e.g., stable cystic fibrosis, severe asthma (continuous or repeated use of systemic corticosteroids), moderate COPD
Diabetes	HbA1c ≥58mmol/mol	All other diabetes (Type 1 and 2)
Immunocompromise due to disease or treatment	Severe e.g., Transplantation: - Listed for solid organ or haematopoietic stem cell transplant (HSCT) - Post solid organ transplant at any time - Post HSCT within 12 months Genetic diseases: - APECED ² - Inborn errors in the interferon pathway - Some B and T cell deficiencies Treatment e.g.: - included but not limited to Cyclophosphamide, Rituximab, Alemtuzumab, Cladribine or Ocrelizumab in the previous 6 months	Other e.g., High dose systemic steroids ³ HIV, not on treatment or CD4 count <200 x10 ⁶ L for adults
Inherited metabolic diseases	Disorders of intermediary metabolism at risk of acute decompensation e.g., Maple Syrup Urine Disease	Disorders of intermediary metabolism not fulfilling criteria for very high risk
Intellectual disability	Down syndrome	Intellectual disability excluding Down Syndrome
Obesity	BMI >40 kg/m ²	BMI >35 kg/m ²
Severe mental illness		e.g., schizophrenia, bipolar disorder, severe depression
Sickle cell disease	Sickle cell disease	

1. Includes e.g., leukaemia, lymphomas, blood dyscrasias or other malignant neoplasms affecting the bone marrow or lymphatic systems

2. APECED - autoimmune polyendocrinopathy candidiasis ecto-dermal dystrophy

3. The following doses of prednisolone (or equivalent dose of another glucocorticoid) are likely to be immunosuppressive:

- Adults and children ≥10kg: ≥40mg/day for more than 1 week, or ≥20mg/day for 2 weeks or longer
- Children <10 kg: 2mg/kg/day for 2 weeks or longer

3. COVID-19 Vaccines

Table 3 shows the vaccines that are recommended by the National Immunisation Advisory Committee (NIAC) following approval by the European Medicines Agency (EMA) that are used in the COVID-19 Immunisation Programme in Ireland.

The following vaccines are no longer available for use in the COVID-19 Immunisation Programme in Ireland:

- Comirnaty® Original 30 micrograms (0.3ml, for those aged 12 years and older)
- Comirnaty® RTU 30 micrograms (0.3ml, for those aged 12 years and older)
- Comirnaty® Original/Omicron BA.1 30 micrograms (0.3ml, for those aged 12 years and older)
- Comirnaty® Original 10 micrograms (0.2ml, for those aged 5-11 years)
- JCOVDEN® (Janssen) (0.5ml, for those aged 18 years and older)
- Spikevax® Original 100 micrograms (0.5ml, for those aged 30 years and older)
- Spikevax® bivalent Original/Omicron BA.1 50 micrograms (0.5ml, for those aged 30 years and older)
- Spikevax® bivalent Original/Omicron BA.4-5 50 micrograms (0.5ml, for those aged 30 years and older)
- Nuvaxovid® (Novavax) (0.5ml, for those aged 12 years and older).
- VidPrevtyl Beta® (for those aged 18 years and older)

Table 3: Vaccines used in the COVID-19 Immunisation Programme

mRNA VACCINES		
Comirnaty® 3mcg	Pfizer/BioNTech	Vaccination of children aged 6 months-4 years
ADAPTED mRNA VACCINES		
Comirnaty® Original/Omicron BA.4-5 30mcg (0.3ml)	Pfizer/BioNTech	<u>May be used for Primary Course and Booster vaccination</u> of individuals aged 12 years and older
Comirnaty® Omicron XBB.1.5 30mcg (0.3ml)	Pfizer/BioNTech	<u>Booster vaccination only</u> of individuals aged 12 years and older
Comirnaty® Original/Omicron BA.4-5 10mcg (0.2ml)	Pfizer/BioNTech	<u>May be used for Primary Course and Booster vaccination</u> of individuals aged 5-11 years
Comirnaty® Omicron XBB.1.5 10mcg (0.2ml)	Pfizer/BioNTech	<u>Booster vaccination only</u> of individuals aged 5-11 years
PROTEIN SUB-UNIT VACCINES		
Nuvaxovid® XBB.1.5 5mcg (0.5ml)	Novavax	<u>Booster vaccination only</u> of individuals aged 12 years and older who cannot receive an adapted mRNA vaccine (because of a contraindication or clinical precaution) or have chosen not to receive an adapted mRNA vaccine

Further regulatory information on COVID-19 vaccines can be found in the approved product information (Summary of Product Characteristics (SmPC) for health care professionals, and Package Leaflet (PIL) for the public), and is available via the EMA website www.ema.europa.eu.

4. Infection Prevention and Control for the administration of COVID-19 Vaccines

Prior to preparation and administration of COVID-19 vaccines, hand hygiene should be performed as per the “WHO five moments of hand hygiene” with emphasis on:

- Before vaccine preparation
- Before drawing up and administering the vaccine
- Before and after each recipient contact

Check Health Protection Surveillance Centre (HPSC) website for latest guidance on infection prevention and control (IPC) for healthcare workers:

National Clinical Guideline No. 30 (2023) – Infection Prevention and Control (IPC)

<https://www.gov.ie/en/publication/a057e-infection-prevention-and-control-ipc/>.

It is not necessary to use a skin disinfectant prior to injection. If the skin at the injection site is visibly dirty, clean with soap and water. If an alcohol swab is used, delay injection for ≥30 seconds, to ensure the alcohol has evaporated.

There is no need to routinely check temperature either at registration or before vaccination.

- Follow HPSC standard precautions (sharps management, Personal Protective Equipment (PPE) and healthcare waste management etc.)
- National Clinical Guideline No. 30 (2023) – Infection Prevention and Control (IPC)
<https://www.gov.ie/en/publication/a057e-infection-prevention-and-control-ipc/>.

5. Vaccine details, storage and instructions for preparation and administration.

Vaccines undergo rigorous checks and quality steps prior to final release from the manufacturer.

SmPCs usually state: "The vaccine should be inspected visually for particulate matter and discolouration prior to administration. Discard the vial if the suspension is discoloured or visible particles are observed." When a vaccinator is concerned regarding a vial the following steps should be followed:

- The vaccinator should contact another healthcare professional (HCP) who has experience in using this product and ask for a second opinion
- The affected vial should be returned to the **fridge** and kept there in **Quarantine** (between +2°C and +8°C)
- The vial in quarantine should be placed in a clearly marked area in the fridge "Quarantine - do not use"
- The vaccinator and senior experienced HCP should check the other vials in this batch in their fridge by removing one vial at a time and ensuring that the duration out of the fridge is kept to a minimum
- If more vials are considered defective, they should calculate the impact of placing vials into quarantine and arrange for additional deliveries if required.
- The Health Products Regulatory Authority (HPRA), manufacturer and HSE National Immunisation Office (NIO) should be emailed with details of the issue and with a photograph of vial identifying the defect (if possible).
- The NIO will follow up and contact other locations where this batch has been delivered if necessary.

Please ensure vaccines are stored between +2°C and +8°C.

Should vaccines be exposed to temperatures outside of these parameters please contact the NIO immediately.

NIO Pharmacists:

Cora Kerrigan: mobile 087 1881565

Leah Gaughan: mobile 087 1881667

Achal Gupta: mobile 087 4064810

Cliona Kiersey

Email pharmacynio@hse.ie

Pre-drawn syringes of COVID-19 vaccines from multi-dose vials that are prepared within designated vaccine preparation areas may be available within the HSE vaccination clinics. National clinical guidance specific to these HSE settings on this matter should be adhered to.



6. Adapted COVID-19 mRNA Vaccines

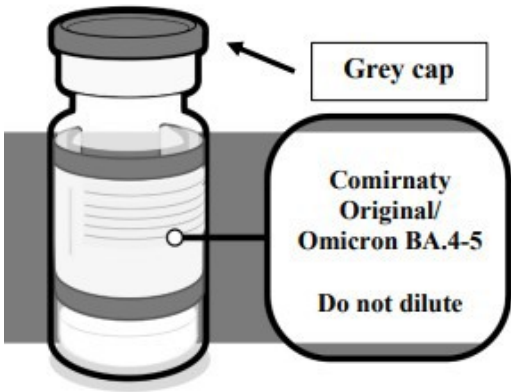
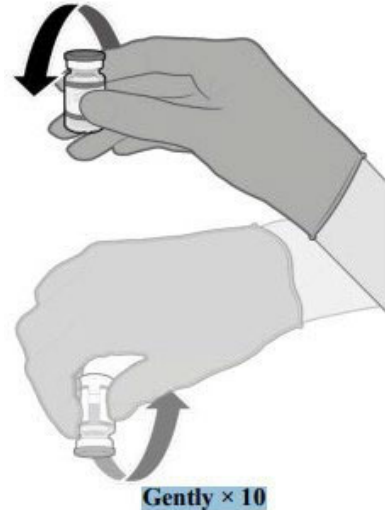
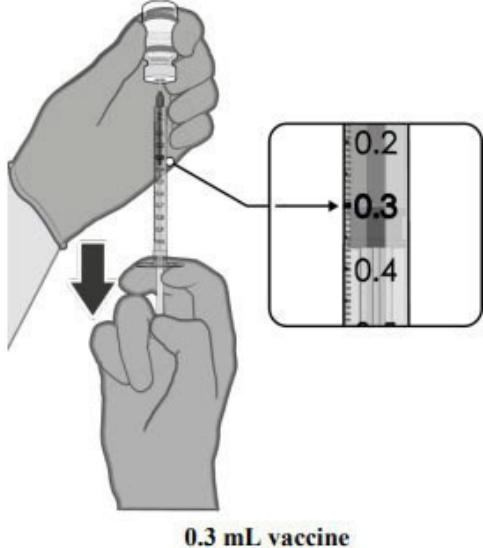
The following vaccines are recommended for Booster vaccination. Please refer to Section 10 for further details

- Comirnaty® Original/Omicron BA.4-5 30 micrograms (0.3ml) is to be used as a primary course for those aged 12 years and older. This formulation may also be used as a booster vaccine for those aged 12 years and older if Comirnaty® Omicron XBB.1.5 30 micrograms (0.3ml) is not available.
- Comirnaty® Omicron XBB.1.5 30 micrograms (0.3ml) is the recommended booster vaccine for those aged 12 years and older

(Of note: For information about vaccines for children aged 5-11 years see Section 14 Vaccination of Children aged 5-11 years).

6.1 Comirnaty® Original/Omicron BA.4-5 30 micrograms (0.3ml)

Title	Description
Manufacturing process	mRNA
Name of vaccines and description	Comirnaty® Original/Omicron BA.4-5 (15/15 micrograms)/dose dispersion for injection.
Indication	Primary vaccination of individuals aged 12 years and older. Can be used as a booster vaccine for those aged 12 years and older if Comirnaty® Omicron XBB.1.5 is not available.
Excipients	<ul style="list-style-type: none"> (4-hydroxybutyl)azanediylbis(hexane-6,1-diyl)bis(2-hexyldecanoate) (ALC- 0315) 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-0159) 1,2-Distearoyl-sn-glycero-3-phosphocholine (DSPC) Cholesterol Trometamol Trometamol hydrochloride Sucrose Water for injections
Presentation	The vaccines are contained in a multi-dose clear glass vial.
Number of doses in each vial	6 doses. If a seventh dose of 0.3ml can be safely and accurately withdrawn from a diluted vial, it is a valid dose. No more than 7 valid doses are available.
Dilution	DO NOT DILUTE
Latex	The vial stopper does not contain latex.
Dosage	0.3ml (30 mcg) intramuscularly

VIAL VERIFICATION OF COMIRNATY ORIGINAL/OMICRON BA 4-5 (12 YEARS AND OLDER)	
	<ul style="list-style-type: none"> • Check “Use before” date and time on the vaccine box • Verify that the vial has a grey plastic cap and a grey border around the label and the product name is Comirnaty® Original/Omicron BA.4-5 (15/15 micrograms)/dose dispersion for Injection.
	<ul style="list-style-type: none"> • Gently mix by inverting vials 10 times prior to use. Do not shake • Prior to mixing, the thawed dispersion may contain white to off-white opaque amorphous particles • After mixing, the vaccine should present as a white to off-white dispersion with no particulates visible. Do not use the vaccine if particulates or discolouration are present
REPARATION OF INDIVIDUAL 0.3 ml DOSES OF COMIRNATY® BA 4-5	
	<ul style="list-style-type: none"> • Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab. • Withdraw 0.3 ml of vaccine. <p>Low dead-volume syringes and/or needles should be used in order to extract 6 doses from a single vial. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial.</p> <ul style="list-style-type: none"> • Each dose must contain 0.3 ml of vaccine. • If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 ml, discard the vial and any excess volume. • Record the appropriate date/time on the vial. Discard any unused vaccine 12 hours after first puncture.

Shelf life and transportation

	Description
Expiry date	The date the vaccine expires when continuously stored in an ULT freezer at -90°C to -60°C. The batch number on the side of each vial is recorded in the patient record. This is linked to the expiry date.
“Use before” date and time Maximum time from removal from ultra-low temperature (ULT) freezer to expiry, when stored at +2°C to +8°C	USE BEFORE date and time. This time and date will be labelled on the box by NCCS. The vials must be used before the use before date and time. The use before date must be recorded in the person’s record
“Discard” date and time Maximum time allowed from first puncture of vial to expiry	After first puncture, the vaccine must be used within 12 hours (when stored at +2 °C to +30 °C) e.g. Vial is punctured 15/05/2023 at 10.00. Discard time is 15/05/2023 at 22.00. This is the date and time that should be written on the vial. Any unused or partially unused vials must be discarded when this time has been reached. From a microbiological point of view, unless the method of opening precludes the risks of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user
Transportation time	Unpunctured vial. No limit within the use before date and time, when stored at +2 to +8 °C Punctured vial Up to 6 hours transportation time within the 12 hour discard date and time when stored at +2 °C to +30 °C.

Comirnaty® BA.4-5 30 micrograms (0.3ml), dosage and scheduling if used for the primary vaccination course for those aged 12 years and older

For those aged 30 years and older

Two doses of 0.3mls Comirnaty® BA.4-5 administered intramuscularly with an interval of 4 weeks between doses. A minimum interval of 3 weeks may be used if there is urgency to achieve protection. The day the first dose is given is day 0.

For those aged 12-29 years

Two doses of 0.3mls Comirnaty® BA.4-5 administered intramuscularly with an interval of 8 weeks between doses. A minimum interval of 3 weeks may be used if there is urgency to achieve protection.

Of note: Those aged under 30 years who receive the primary course at less than the recommended 8 week interval should be advised of the potential increased risk of myocarditis.

For those who are immunocompromised with a suboptimal response to vaccines (see Table 2) aged 12 years and older

Three doses of 0.3mls Comirnaty® BA.4-5 administered intramuscularly with an interval of 4 weeks between dose one and dose two, and eight weeks between dose two and dose three. A minimal interval of 4 weeks between the second and third dose may be used if there is urgency to achieve protection.

Further information on the interval between 2 doses for primary vaccination with Comirnaty® BA.4-5 30 micrograms for those aged 12 years and older

If the interval between doses is longer than the recommended interval, the next dose should be given as soon as possible. The course does not need to be restarted.

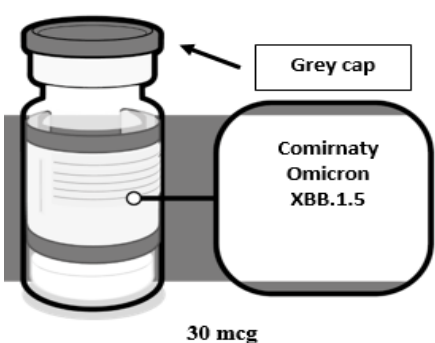

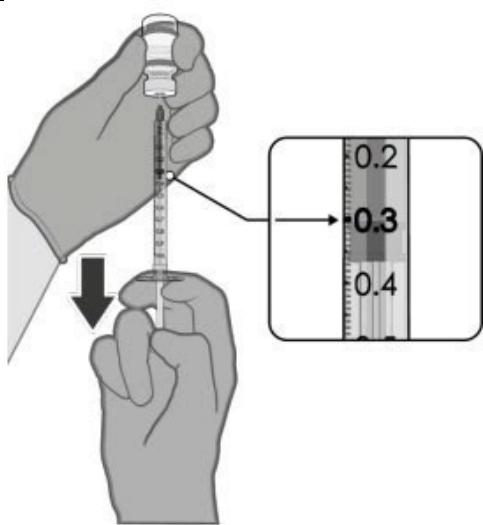
If the second dose is given more than 4 days before the minimum interval, this is not considered a valid dose. A third dose should be given at least 4 weeks after the second (invalid) dose for those aged 30 years and older, or at least 8 weeks after the second (invalid) dose for those aged less than 30 years. A minimum interval of 21 days may be used if there is urgency to achieve protection.

Table 4: Interval between 2 doses for primary vaccination with Comirnaty® BA.4-5 30 micrograms for those aged 12 years and older

Interval between 1st and 2nd Doses	Action required
Less than 17 days	This is not considered a valid dose. A third dose should be given at least 4 weeks after the second (invalid) dose for those aged 30 years and older, or at least 8 weeks after the second (invalid) dose for those aged 12-29 years. A minimum interval of 21 days may be used if there is urgency to achieve protection.
17 days to 4 weeks for those aged 30 years and older	No further action needed. This is a valid vaccine.
17 days to 8 weeks for those aged 12-29 years	No further action needed. This is a valid vaccine.
Longer than 4 weeks for those aged 30 years and older	Give the second dose as soon as possible. The course does not need to be restarted.
Longer than 8 weeks for those aged 12-29 years	Give the second dose as soon as possible. The course does not need to be restarted.

6.2 Comirnaty® Omicron XBB.1.5 30 micrograms (0.3ml)

Title	Description
Manufacturing process	mRNA
Name of vaccines and description	Comirnaty® Omicron XBB.1.5 30 micrograms/dose dispersion for injection
Indication	Booster vaccination of individuals aged 12 years and older
Excipients	<ul style="list-style-type: none"> • ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) (ALC-0315) • 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-0159) • 1,2-Distearoyl-sn-glycero-3-phosphocholine (DSPC) • Cholesterol • Trometamol • Trometamol hydrochloride • Sucrose • Water for injections
Presentation	The vaccines are contained in a multi-dose clear vial (type I glass)
Number of doses in each vial	<p>6 doses.</p> <p>If a seventh dose of 0.3ml can be safely and accurately withdrawn from a diluted vial, it is a valid dose.</p> <p>No more than 7 valid doses are available.</p>
Dilution	DO NOT DILUTE
Latex	The vial stopper does not contain latex.
Dosage	0.3ml (30 mcg) intramuscularly

VIAL VERIFICATION OF COMIRNATY OMICRON XBB.1.5 (12 YEARS AND OLDER)	
 <p>30 mcg</p>	<ul style="list-style-type: none"> • Check “Use before” date and time on the vaccine box • Verify that the vial has a grey plastic cap and the product name is Comirnaty® Omicron XBB.1.5 30 micrograms/dose dispersion for injection.
 <p>Gently × 10</p>	<ul style="list-style-type: none"> • Gently mix by inverting vials 10 times prior to use. Do not shake • Prior to mixing, the thawed dispersion may contain white to off-white opaque amorphous particles • After mixing, the vaccine should present as a white to off-white dispersion with no particulates visible. Do not use the vaccine if particulates or discolouration are present.
REPARATION OF INDIVIDUAL 0.3 ml DOSES OF COMIRNATY OMICRON XBB.1.5	
 <p>0.3 mL vaccine</p>	<ul style="list-style-type: none"> • Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab. • Withdraw 0.3 ml of vaccine. <p>Low dead-volume syringes and/or needles should be used in order to extract 6 doses from a single vial. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial.</p> <ul style="list-style-type: none"> • Each dose must contain 0.3 ml of vaccine. • If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 ml, discard the vial and any excess volume. • Record the appropriate date/time on the vial. Discard any unused vaccine 12 hours after first puncture.

Shelf life and transportation

	Description
Expiry date	The date the vaccine expires when continuously stored in an ULT freezer at -90°C to -60°C. The batch number on the side of each vial is recorded in the patient record. This is linked to the expiry date.
“Use before” date and time Maximum time from removal from ultra-low temperature (ULT) freezer to expiry, when stored at +2°C to +8°C	USE BEFORE date and time. This time and date will be labelled on the box by NCCS. The vials must be used before the use before date and time. The use before date must be recorded in the person’s record.
“Discard” date and time Maximum time allowed from first puncture of vial to expiry	<p>After first puncture, the vaccine must be used within 12 hours (when stored at +2 °C to +30 °C) e.g. Vial is punctured 15/09/2023 at 10.00. Discard time is 15/09/2023 at 22.00. This is the date and time that should be written on the vial. Any unused or partially unused vials must be discarded when this time has been reached.</p> <p>From a microbiological point of view, unless the method of opening precludes the risks of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user</p>
Transportation time	<p>Unpunctured vial. No limit within the use before date and time, when stored at +2 to +8 °C</p> <p>Punctured vial Up to 6 hours transportation time within the 12 hour discard date and time when stored at +2 °C to +30 °C.</p>

7. Protein Sub-Unit Vaccine: Nuvaxovid® XBB.1.5



This vaccine is currently used as a **booster vaccine only** in people aged 12 years and older who cannot receive an adapted mRNA COVID-19 vaccine because of a contraindication or a precaution, or in people who have chosen not to receive an adapted mRNA COVID-19 booster vaccine.

Table 5: Details of Nuvaxovid® XBB.1.5 for Booster vaccination

Title	Description
Type of vaccine	Protein sub-unit vaccine
Name of vaccine	Nuvaxovid®XBB.1.5 dispersion for injection COVID-19 Vaccine (recombinant, adjuvanted)
Constituents	<p>One dose (0.5 ml) contains 5 micrograms SARS-CoV-2 (Omicron XBB.1.5) spike protein* and is adjuvanted with Matrix-M.</p> <ul style="list-style-type: none"> Disodium hydrogen phosphate heptahydrate Sodium dihydrogen phosphate monohydrate Sodium chloride Polysorbate 80 Sodium hydroxide (for adjustment of pH) Hydrochloric acid (for adjustment of pH) Water for injections <p><u>Adjuvant (Matrix-M)</u></p> <ul style="list-style-type: none"> Matrix-M adjuvant contains Fraction-A (42.5 micrograms) and Fraction-C (7.5 micrograms) of Quillaja saponaria Molina extract per 0.5 ml dose. Cholesterol Phosphatidylcholine (including all-rac-α-Tocopherol) Potassium dihydrogen phosphate Potassium chloride Disodium hydrogen phosphate dihydrate Sodium chloride Water for injections
Presentation	2.5 ml of dispersion in a vial (type I glass). The dispersion is colourless to slightly yellow, clear to mildly opalescent
Number of doses in each vial	<p>Up to 5 doses</p> <p>If more than five 0.5ml doses can be safely and accurately withdrawn from a vial, they can be used as valid vaccines.. There should be no pooling of vaccine from different vials</p>
Dilution	NO DILUTION REQUIRED
Latex	<p>No, the vaccine is latex free</p> <p>Each vial has a stopper (bromobutyl rubber) and an aluminium overseal with blue plastic flip-off cap</p>
Dosage	0.5 ml
Number of doses required	1

* produced by recombinant DNA technology using a baculovirus expression system in an insect cell line that is derived from Sf9 cells of the *Spodoptera frugiperda* species.

Nuvaxovid® XBB.1.5 storage

The vaccine will be delivered by the NCCS at +2°C to +8°C.

Unopened (unpunctured) multidose vial should be stored in a pharmaceutical grade refrigerator (+2°C to +8°C) until expiry.

Unopened vaccine should be kept within the outer carton to protect from light. Unopened Nuvaxovid XBB.1.5 vaccine has been shown to be stable up to 12 hours at 25°C.

Opened multi-dose vial

Chemical and physical in-use stability has been demonstrated for **6 hours at +2°C to +25°C** from the time of first needle puncture to administration. The “discard” date and time i.e. 6 hours after the vial is first punctured must be written on the vial using a 24 hour format.

Table 6: Definitions of terms for expiry date and usage times of Nuvaxovid® XBB.1.5

	Description
Expiry date	This is date after which the vial must not be punctured. It is printed on the vaccine vial and original box
“Discard” date and time Maximum time allowed from first puncture to vaccine administration	When the vaccine is first punctured it must be used within 6 hours. The “discard” date and time i.e. 6 hours from first puncture of the vial, should be written on the vial using a 24 hour format. E.g. Vial is first punctured on 20/12/2023 at 10.00. Discard date and time is 20/12/2023 at 16.00. This is the date and time that should be written on the vial. Any unused or partially used vials must be discarded when this time has been reached.

Preparation and administration of Nuvaxovid® XBB.1.5

Vaccine dose preparation and administration should be carried out at the point of administration i.e. beside the person being vaccinated.

- The same needle and syringe should be used to draw up and administer the vaccine
- Once the multidose vial is punctured, the vaccine should be used immediately. If not used, it may be kept for a single period between +2°C to +25°C and used within six hours. There should be no pooling of vaccine from different vials

Requirements for administration of vaccine

- One Nuvaxovid® XBB1.5 multidose vial
- 70% alcohol swabs
- Size 23 gauge / 25 gauge and 25mm in length needle
- 1ml syringes

Note: A 40 mm needle should be used in females >90kg and males >120kg

Preparation and administration of one dose of vaccine

Preparation for use:

- The vaccine comes ready to use.
- Unopened vaccine should be stored at +2°C to +8°C and kept within the outer carton to protect from light.
- Immediately prior to use, remove the vaccine vial from the carton in the refrigerator.
- Record the date and time of discard on the vial label. Use within 6 hours after first puncture.

Inspect the vial:

- Gently swirl the multidose vial before and in between each dose withdrawal. Do not shake.
- Each multidose vial contains a colourless to slightly yellow, clear to mildly opalescent dispersion free from visible particles.
- Visually inspect the contents of the vial for visible particulate matter and/or discolouration prior to administration. Do not administer the vaccine if either is present.

Administer the vaccine:

- Each 0.5 ml dose is withdrawn into a sterile needle and sterile syringe to be administered by intramuscular injection, preferably in the deltoid muscle of the upper arm.
- Do not mix the vaccine in the same syringe with any other vaccines or medicinal products.
- Do not pool excess vaccine from multiple vials.

Storage after first needle puncture:

- Nuvaxovid does not contain a preservative. Store the opened vial between +2°C to +25°C for up to 6 hours after first puncture

Discard:

- Discard this vaccine if not used within 6 hours after first puncture of the vial
- Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Nuvaxovid® XBB.1.5 dosage and site of administration for booster vaccination

The booster dose of 0.5ml should be administered intramuscularly. The preferred site of administration is the deltoid muscle.

Nuvaxovid XBB.1.5 may be used for homologous and heterologous boosters. Booster doses are recommended as per Table 1 of this document (or Table 5a.1 of Chapter 5a of the NIAC Immunisation Guidelines for Ireland).

If there is a contraindication or precaution to an adapted mRNA vaccine booster, or a person has chosen not to receive an adapted mRNA COVID-19 vaccine booster, Nuvaxovid XBB.1.5 may be used as an alternate. Please refer to section 10 for more information on booster vaccination with Nuvaxovid XBB.1.5.

8. Contraindications and precautions to COVID-19 vaccines

8.1 mRNA Vaccines

Contraindications to mRNA vaccines

- Anaphylaxis (serious systemic allergic reaction requiring medical intervention) after an mRNA vaccine
- Anaphylaxis after polyethylene glycol (PEG, e.g., some bowel preparations for endoscopy, certain laxatives such as Movicol)
- Anaphylaxis after trometamol¹, (contained in all presentations of Comirnaty® currently in use in Ireland)

Those with a contraindication to one mRNA COVID-19 vaccine should not receive another authorised mRNA vaccine.

Consideration may be given to non-mRNA vaccination for anyone aged 12 years and older following an individual benefit risk assessment, including pregnant women. This should be given after an interval of at least 4 weeks following a previous vaccination, and the person should be considered fully vaccinated.

Currently, only mRNA **Comirnaty® Original/Omicron BA.4-5** vaccines are available for primary vaccination in Ireland. There are no non-mRNA vaccines available for primary vaccination.

If there is a contraindication or precaution to an adapted mRNA vaccine booster, or a person has chosen not to receive an adapted mRNA COVID-19 vaccine booster, Nuvaxovid XBB.1.5 (a protein based vaccine) may be used as an alternate following an individual benefit risk assessment. There is more limited experience of Nuvaxovid XBB.1.5 in those who are pregnant, and this should only be considered when the potential benefits outweigh the potential risks.

Precautions:

- Acute severe illness; defer until recovery. Routine physical examination and temperature measurement of persons who appear to be healthy are not necessary prior to vaccination.
- Previous history of myocarditis or pericarditis after any COVID-19 vaccine - seek specialist advice before vaccination (i.e., consult with a Cardiologist).
- There should be an interval of at least 4 weeks between mpox (formerly known as monkeypox)/smallpox vaccine and a subsequent COVID-19 vaccine because of the unknown risk of myocarditis.
- Children with a previous history of MIS-C - defer vaccination until clinical recovery or at least 3 months since diagnosis, whichever is the longer.
- Consider a non-mRNA booster vaccine (Nuvaxovid® XBB.1.5) for those aged 12 years and

¹ Trometamol has been implicated in one report of contrast medium anaphylaxis relating to gadolinium based contrast agents (GBCAs) used in MRI radiological studies.

older, including pregnant women, with:

- Anaphylaxis after multiple different drug classes, with no identified allergen (may indicate PEG allergy)
- Anaphylaxis after a vaccine or a medicine known to contain PEG
- Unexplained anaphylaxis (may indicate PEG allergy)

If there is a precaution to a booster mRNA vaccine, consideration can be given to boosting with an EMA authorised non-mRNA vaccine following an individual benefit risk assessment.

Patients with planned immunosuppressive therapy should ideally complete vaccination two weeks before treatment. The recommended minimum interval may be used. Specialists should consider the individual's risk and likelihood of disease exposure, and provide advice based on knowledge and understanding of the patient's immune status and likely immune response to vaccination.

For more information please refer to the NIAC Immunisation Guidelines for Ireland **Table 5a.3 Contraindications and precautions to mRNA COVID-19 vaccines** and see Frequently Asked Questions about COVID-19 vaccines for people with pre-existing allergic conditions www.rcpi.ie

Of note: Refer to section 14 for details of vaccination of children aged 5-11

Refer to section 15 for details of vaccination of children aged 6 months-4 years

8.2 Protein sub-unit vaccine Nuvaxovid® XBB.1.5

Contraindications

Anaphylaxis (serious systemic allergic reaction requiring medical intervention) following a previous dose of the vaccine or any of its constituents including polysorbate 80.

Precautions

Acute severe illness; defer until recovery.

Previous history of myocarditis or pericarditis after any COVID-19 vaccine, seek specialist advice.

There should be an interval of 4 weeks between mpox (formerly known as monkeypox)/smallpox vaccine and a subsequent Nuvaxovid XBB.1.5 vaccine because of the unknown risk of myocarditis. No interval is required between Nuvaxovid XBB.1.5 and subsequent mpox vaccines.

Advice from a relevant specialist should be sought for a person with:

- a history of an immediate severe allergic reaction to multiple drug classes with no identified allergen,
- any other vaccine injected antibody preparation or medicine likely to contain polysorbate 80 or
- idiopathic anaphylaxis

The risks should be weighed against the benefits of vaccination.

There is more limited experience of Nuvaxovid XBB.1.5 in those who are pregnant, and this should only be considered when the potential benefits outweigh the potential risks.

Please refer to the NIAC Immunisation Guidelines for Ireland for details. <https://www.rcpi.ie/healthcare-leadership/niac/immunisation-guidelines-for-ireland>

Appropriate support should be available in case of anaphylaxis or fainting after vaccine administration. Precautions should also be in place to minimise risk of injury from fainting.

8.3 Vaccination after COVID-19 (primary vaccination course)

Unvaccinated

Those who are unvaccinated and develop SARS-CoV-2 infection should complete a primary vaccination course, with the first dose at least four weeks after diagnosis or onset of symptoms, or four weeks from the first PCR positive specimen in those who are asymptomatic.

Those with persisting symptoms following COVID-19 may be vaccinated, unless there is evidence of recent clinical deterioration.

Partially vaccinated

Those who have had SARS-CoV-2 infection after their first dose of COVID-19 vaccine should be given the subsequent dose at least four to eight weeks (age dependent) after diagnosis or onset of symptoms.

If those who are immunocompromised have SARS-CoV-2 infection more than seven days after the second vaccine dose, a third dose of the primary series is not required. They should proceed to their first booster dose as per Table 1 of this document (or Table 5a.1 of the NIAC Immunisation Guidelines for Ireland). For those with infection within seven days of their second dose they should complete the extended primary series after an interval of 4-8 weeks.

9. Clinical considerations for COVID-19 vaccines

9.1 Pregnancy

Pregnant women should be offered mRNA COVID-19 vaccines and should be up to date with COVID-19 vaccines in line with NIAC recommendations. For details of the recommended timing of booster vaccination in pregnancy please see Section 10.

Pregnant women should be offered mRNA COVID-19 vaccines at any stage of pregnancy for:

- their primary vaccination course (if unvaccinated)
- the additional mRNA vaccine dose recommended for immunocompromised after the appropriate interval (if immunocompromised and pregnant)

Continuing evidence regarding mRNA COVID-19 vaccination during pregnancy has demonstrated it to be safe and effective. The primary schedule may be given at any stage in pregnancy with an interval as recommended in Table 1.

Pregnant women are at similar risk of COVID-19 infection to non-pregnant women of the same age.

However, pregnant women with COVID-19 infection are more likely to be admitted to ICU or to die than similar aged non-pregnant women with COVID-19. Pregnant women from Black, Asian and minority ethnic backgrounds may be more likely to be admitted to hospital with COVID-19 disease than other pregnant women.

COVID-19 in pregnancy may increase the risk of adverse pregnancy outcomes, such as miscarriage, stillbirth and preterm birth.

The following factors may increase the risks of severe illness in pregnancy:

- Underlying conditions listed in Table 5a.2 of the NIAC Immunisation Guidelines for Ireland
- Age over 35 years
- Infection in the third trimester (28 weeks' or more)
- BMI of 30 or more.

There is now a growing body of evidence on the safety and effectiveness of mRNA COVID-19 vaccination - clearly indicating that the benefits of vaccination outweigh any known or potential risks of COVID-19 vaccination during pregnancy. Long term follow-up is on-going.

Vaccination is the best way to protect both mother and baby from serious harm and mRNA vaccines should be available to pregnant women at all stages of pregnancy. Emerging data indicates that the maternal COVID-19 antibodies can cross the placenta, which may offer neonatal protection.

The NIAC has reviewed the evidence regarding safety and timing of COVID-19 primary and booster vaccines in pregnancy. Current data are very reassuring regarding the safety of COVID-19 mRNA vaccines given at any stage in pregnancy either as a primary series or as a booster. The EMA, UK Health Security Agency, and CDC

have been monitoring the safety of COVID-19 vaccines in pregnancy^{2,3,4}. These safety monitoring systems have not reported any safety concerns for people who receive an mRNA COVID-19 vaccine at any stage of pregnancy. Less data are available regarding non-mRNA vaccines.

NIAC and the Institute of Obstetricians and Gynaecologists have developed materials to support healthcare workers and pregnant women in decision making about COVID-19 vaccination. Visit www.rcpi.ie.

Please refer to Section 10 for further details of booster vaccinations.

Booster vaccination in pregnancy with Nuvaxovid® XBB.1.5

There is limited experience with use of the vaccine in pregnant women.

Administration of Nuvaxovid XBB.1.5 in pregnancy should only be considered when the benefits outweigh the potential risks to the mother and the fetus and when booster mRNA vaccines are contraindicated or declined. The pregnant woman and a relevant health professional should engage in shared decision-making in advance of vaccination. Counselling should balance the available data on vaccine safety, risks to pregnant women from COVID-19 infection, and a woman's individual risk for infection and severe disease.

mRNA vaccines remain the recommended COVID-19 vaccines for pregnant women as they have the most extensive safety and efficacy data. If there is a contraindication or precaution to an adapted booster mRNA vaccine, or a pregnant person has chosen not to receive an adapted mRNA COVID-19 booster vaccine, vaccination with Nuvaxovid XBB.1.5 may be considered following an individual benefit risk assessment.

9.2 Breastfeeding

COVID-19 vaccines can be used during breastfeeding. There is no evidence that breastfeeding after COVID-19 vaccination causes harm to the breastfed infants or interferes with ability to breastfeed.

9.3 Fertility

There is no evidence that any COVID-19 vaccine affects fertility or the fetus. No unexpected pregnancy or infant outcomes have been observed related to COVID-19 vaccination during pregnancy. There is no biologically plausible reason why any of the COVID-19 vaccines would

² European Medicines Agency. COVID-19: latest safety data provide reassurance about use of mRNA vaccines during pregnancy 2022 [Available from: <https://www.ema.europa.eu/en/news/covid-19-latest-safety-data-provide-reassurance-about-use-mrna-vaccines-during-pregnancy> accessed 21 Feb 2023].

³ Agency UHS. COVID-19 vaccine surveillance report. Week 5, 2 February 2023 2023 [Available from: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1134076/vaccine-surveillance-report-week-5-2023.pdf accessed 21 Feb 2023].

⁴ Centres for Disease Control and Prevention. COVID-19 Vaccines While Pregnant or Breastfeeding 2022 [Available from: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/pregnancy.html> accessed 21 Feb 2023].

have any effect on fertility. There is no evidence that any of the COVID-19 vaccines have any effect on fertility.

9.4 Individuals with a bleeding disorder

Individuals with a bleeding disorder or receiving anticoagulant therapy may develop haematomas in IM injection sites. Prior to vaccination, inform the recipient about this risk. For those with thrombocytopenia (platelet count $<50 \times 10^9/L$) consult the supervising consultant.

People with mild bleeding disorders or on maintenance dose Emicizumab (Hemlibra®) do not require haemostatic cover for vaccination. Details of haemostatic cover for all others can be found in the Patient Information tab at <http://www.stjames.ie/services/hope/nationalcoagulationcentre>

Those with inherited coagulopathies receiving factor replacement therapy should receive the treatment on the day of vaccination, prior to the IM vaccination.

If there is uncertainty about the need for cover, contact the patient's Comprehensive Care Centre.

9.5 Individuals taking anticoagulants

Those receiving long term anticoagulation with either warfarin or heparin are not considered to be at higher risk of bleeding complications following immunisation. There is no reason to expect that there is a greater risk of bleeding complications with the newer types of anticoagulants, such as antiplatelet agents, than with other anticoagulants.

People on Warfarin® should follow their usual schedule for international normalised ratio (INR) testing and can be vaccinated if it is less than 4.0. If the INR is 4.0 or more, follow the advice of the clinic/practice managing Warfarin® and wait until the INR is less than 4.0 to be vaccinated.

9.6 Technique for IM injections in persons with bleeding disorders or on anticoagulants

- Use a 23 or 25 gauge needle to reduce the pressure gradient and cause less trauma to the tissue.
- The vaccine should be injected slowly (≥ 5 seconds) to reduce the risk of tissue damage.
- Firm pressure should be applied to the site for 5 to 10 minutes after injection.
- Stabilisation of the limb will reduce the risk of a haematoma.
- The site should not be rubbed or massaged.
- Instruct the patient/caregiver to monitor the injected limb and to report any concerns to their supervising consultant.

9.7 Co-administration of COVID-19 vaccines with other inactivated or live vaccines for those aged 12 years and over:

COVID-19 and adult seasonal influenza vaccines should be co-administered where practicable, to maximise uptake. Vaccinees should be informed there may be a slight increase in short term mild adverse events after co-administration with a seasonal influenza vaccine. These include pain at the site of injection, fatigue, headache, and myalgia.

There should be an interval of at least four weeks between mpox vaccine and a subsequent COVID-19 vaccine because of the unknown risk of myocarditis. No interval is required between a COVID-19 vaccine and a subsequent mpox vaccine.

COVID-19 vaccines and other adult vaccines may be administered at the same time or at any interval. Co-administered vaccines should be given in different arms.

9.8 Immunosuppression due to disease or treatment

Individuals with immunosuppression due to disease or treatment should be vaccinated if they have no contraindications.

Patients with planned immunosuppressing therapy should ideally complete vaccination two weeks before treatment. The recommended minimum interval may be used.

Specialists should consider the individual's risk and likelihood of disease exposure, and provide advice based on knowledge and understanding of the patient's immune status and likely immune response to vaccination.

9.9 Extended primary course for those with immunosuppression due to disease or treatment: mRNA vaccines

Those with severe immunocompromise (see Table 5a.2 of the NIAC Immunisation Guidelines for Ireland) due to disease or treatment at the time of their primary COVID-19 vaccination may have suboptimal response to their vaccines. There is evidence that protection can be enhanced by an additional mRNA vaccine dose, representing an extension of the primary vaccination series.

An additional mRNA vaccine dose should be given to those aged 12 years and older with immunocompromise associated with a suboptimal response to vaccines at the time of vaccination who have completed their primary course. Serological testing prior to giving an additional dose is not recommended.

Recommended intervals for the extended 3 dose primary series for those with immunocompromise:

Three doses, with a 4 week interval between dose one and two, and 8 weeks between dose two and three. i.e.

- An **interval of 4 weeks** between the first and second doses of an mRNA vaccine is now recommended (a minimum interval of 3 weeks may be used if there is urgency to achieve protection)
- This is then followed by **the additional dose** (or third dose of the extended primary vaccination series). The additional dose should be given **8 weeks** after the second vaccine dose (a minimal interval of 4 weeks between the second and third dose may be used if there is urgency to achieve protection).

See [Table 5a.2 of the NIAC Immunisation Guidelines for Ireland](#) for conditions that may be associated with a suboptimal response to vaccines (shaded in blue in the table)

9.10 Vaccination with the additional dose after breakthrough infection

If those who are immunocompromised have SARS-CoV-2 infection more than seven days after the second vaccine dose, a third dose of the primary series is not required. They should proceed to their first booster dose as per Table 1 (or Table 5a.1 of the NIAC Immunisation Guidelines for Ireland). For those with infection within seven days of their second dose they should complete the extended primary series after an interval of 4-8 weeks. If it is not

possible to establish if an individual had breakthrough infection during that timeframe, they may be vaccinated.

Please refer to section 9.1 for details of vaccination in pregnancy.

9.11 People being treated with chemotherapy for cancer

Chemotherapy is not a contraindication to COVID-19 vaccination. People taking chemotherapy should be vaccinated according to their priority group (provided there are no contraindications).

9.12 Heterologous vaccination

The same vaccine should preferably be used for both doses of a primary vaccination course. NIAC advise that those who have partially completed a COVID-19 vaccine course with a vaccine authorised by the FDA, MHRA or recommended by WHO, should be offered an EMA authorised COVID-19 vaccine to complete the course, and then should be considered fully vaccinated. The minimum interval between the last vaccine dose and an EMA authorised COVID-19 vaccine is 4 weeks.

9.13 Recommendations for primary COVID-19 vaccination, first boosters and further boosters in Autumn 2023

For NIAC recommendations for primary COVID-19 vaccination, first boosters and further boosters in Autumn 2023, please see Table 1.

Vaccination for children aged 5-11 years is discussed in a separate section within this guidance document (see Section 14).

10. **Booster COVID-19 Vaccines**

Irrespective of the vaccine type used in the primary schedule, **mRNA vaccines are the preferred vaccines as boosters**. Nuvaxovid XBB.1.5 may be used as an alternate booster vaccine (following an individual benefit-risk assessment) if mRNA vaccines are contraindicated or not accepted.

Booster doses of an mRNA vaccine are recommended as outlined below.

For those aged 18 years and older:

A first booster dose is recommended for all those aged 18 years and older as it has an important role in enhancing and extending protection gained from the primary schedule.

Further booster doses should be given as per the recommendations in Table 1.

For those aged 12-17 years:

A first booster dose is available to all those aged 12-17 years and is recommended for those with immunocompromise.

Further booster doses should be given as per the recommendations in Table 1.

The following adapted mRNA vaccines are available in Ireland for booster vaccination of those **aged 12 years and older**:

- **Comirnaty® Omicron XBB.1.5 30 micrograms (0.3ml)**
- **Comirnaty® Original/Omicron BA.4-5 30 micrograms (0.3ml)**

NOTE: Comirnaty® Omicron XBB.1.5 30 micrograms is the preferred booster vaccination for this age group. However, if Comirnaty® Omicron XBB.1.5 30 micrograms is not available, then Comirnaty® Original/Omicron BA.4-5 30 micrograms may be used for booster vaccination.

The National Immunisation Advisory Committee (NIAC) recommends the preferential use of Comirnaty® Omicron XBB.1.5 30 micrograms for booster vaccination in Ireland.

In December 2022, the European Medicines Agency's (EMA) Emergency Task Force concluded that **Comirnaty® Original/Omicron BA.4-5 vaccines may be used when necessary in primary vaccination of previously unvaccinated children and adults.**

Recommended intervals for first boosters following primary course vaccination:

- At least 4 months after the last dose of a COVID-19 vaccine. In exceptional circumstances a 3 month interval may be used. If a booster dose was given in error before the minimum 3 month interval, this is not considered a valid vaccine. However, revaccination is not recommended.

Recommended intervals for further booster vaccination in Autumn 2023 for those aged 12 years and older:

Please see [Table 1](#) for those who are recommended to receive further booster vaccines in Autumn 2023.

- A **6 month** interval from previous COVID-19 booster vaccine or infection is recommended for those aged 50 years and older receiving a further booster as part of the Autumn vaccination programme 2023.
- A **9 month** interval from previous COVID-19 booster vaccine or infection is recommended for those aged under 50 years receiving a further booster as part of the Autumn vaccination programme 2023 (except in the case of those aged 12 years and older with immunocompromise associated with a suboptimal response to vaccination, for whom an interval of **6 months** following any previous COVID-19 vaccine dose or infection is recommended).
- A minimum interval of **3 months** is permissible in exceptional circumstances e.g. heightened epidemiologic risk or for operational reasons.

Booster Vaccination after COVID-19 breakthrough infection

Those who have had SARS-CoV-2 infection after completing their primary series (i.e., a breakthrough infection), should proceed to booster vaccination as recommended in Table 1 (or Table 5a.1 of the NIAC Immunisation Guidelines for Ireland).

Safety of booster doses of mRNA vaccines

- First and second booster doses of mRNA vaccines have not shown any unexpected safety concerns. Myocarditis and pericarditis are very rare risks of mRNA vaccination, predominantly in males aged under 30 years after the second dose of the primary vaccination course and the risk appears to be comparatively lower following a first booster dose.
- Data on second booster doses is more limited but experience has not revealed any new safety concerns.
- As the adapted vaccines are adaptations of the original COVID-19 vaccine for which the safety profile is well established, it is expected that their safety profile will be similar.
- In authorising the BA.4-5 bivalent vaccines, the EMA based their recommendations on safety of the bivalent BA.1 mRNA COVID-19 vaccines and long term data on previous mRNA vaccines.
- The safety of Comirnaty® Omicron XBB.1.5 is inferred from safety data of the prior Comirnaty® vaccines.

Booster vaccination with Nuvaxovid® XBB.1.5

Booster doses of Nuvaxovid XBB.1.5 are recommended as per Table 1 (or Table 5a.1. of the NIAC Immunisation Guidelines for Ireland). Nuvaxovid XBB.1.5 may be used for homologous and heterologous boosters (in those aged 12 years and older).

If there is a contraindication or precaution other than myocarditis or pericarditis to a booster dose of an adapted mRNA vaccine, or a person has chosen not to receive an adapted mRNA COVID-19 booster, consideration can be given to a homologous or heterologous booster of Nuvaxovid XBB.1.5 following an individual benefit-risk assessment.

For information on recommended intervals for Nuvaxovid XBB.1.5 boosters see Table 1.

In exceptional circumstances an interval of 3 months may be used (e.g., in a person scheduled to commence chemotherapy).

There is more limited experience of Nuvaxovid XBB.1.5 in those who are pregnant, and this should only be considered when the potential benefits outweigh the potential risks. If pregnant women are receiving Nuvaxovid® XBB.1.5 as a booster dose, they should have a discussion with a healthcare professional (e.g. clinical lead vaccinator) on their individual risks and benefits of receiving the vaccine. Please refer to section 9.1.

Table 7. Adapted Vaccine Summary

Description	Comirnaty® Original/ Omicron BA.4-5 30 micrograms (0.3ml)	Comirnaty® Omicron XBB.1.5 30 micrograms (0.3ml)	Nuvaxovid® XBB.1.5 5 micrograms (0.5ml)
Vial cap colour	Grey cap	Grey cap	Blue cap
Indication for booster vaccination	Aged 12 years and older MAY BE USED FOR PRIMARY COURSE AND BOOSTER VACCINATION <i>MAY ALSO BE USED FOR ADDITIONAL DOSE</i>	Aged 12 years and older USE FOR BOOSTER VACCINATION ONLY	Aged 12 years and older USE FOR BOOSTER VACCINATION ONLY
Dose volume (dose)	0.3ml (30mcg)	0.3ml (30mcg)	0.5ml (5mcg)
Dilution	READY TO USE DO NOT DILUTE	READY TO USE DO NOT DILUTE	READY TO USE DO NOT DILUTE
Doses per vial	6	6	5
Interval since last dose of COVID-19 Vaccine	For Booster dose: At least 4 months for first booster* (3 months in exceptional circumstances)	At least 4 months for first booster* (3 months in exceptional circumstances)	At least 4 months for first booster* (3 months in exceptional circumstances)

* A 6 month interval from previous booster vaccine or infection is recommended for those aged 50 years and older receiving a further booster as part of the Autumn vaccination programme 2023. A 9 month interval from previous booster vaccine or infection is recommended for those aged 12-49 years receiving a further booster as part of the Autumn vaccination programme 2023 (except in the case of those aged 12 years and older with immunocompromise associated with a suboptimal response to vaccination, where an interval of 6 months is recommended).

OF NOTE: For information about the adapted booster vaccines for children aged 5-11 years see Section 14 Vaccination of Children aged 5-11 years.

Please refer to section 5 for details of preparation, transport and storage of vaccine

Booster Vaccination in pregnancy

The NIAC have reviewed the evidence regarding safety and timing of COVID-19 primary and booster vaccines in pregnancy. Current data are very reassuring regarding the safety of COVID-19 mRNA vaccines given at any stage of pregnancy either as a primary series or as a booster. Less data are available regarding non-mRNA vaccines. mRNA COVID-19 vaccines remain the preferred option for use in pregnancy. The NIAC now recommend:

For pregnant adolescents and adults, a COVID-19 booster vaccine is recommended once in pregnancy. If a pregnant person has not had a previous COVID-19 booster, the **first booster dose** is recommended at least **4 months** after their last COVID-19 vaccine dose or SARS-CoV-2 infection.

For those who have had a booster prior to pregnancy, they should receive a booster once in pregnancy at an interval of **6 months or more** since their last booster dose or SARS-CoV-2 infection. Booster doses can be given at any stage in pregnancy but ideally should be given between 20-34 weeks. If it is more than 12 months since their previous COVID-19 vaccine or infection administration earlier in pregnancy should be considered.

For those who are pregnant and are immunocompromised, a second booster dose within the same pregnancy may be considered if **6 months** has elapsed since their last booster dose or SARS-CoV-2 infection.

There is more limited experience of Nuvaxovid XBB.1.5 in those who are pregnant, and this should only be considered when the potential benefits outweigh the potential risks.

11. Post Vaccination

11.1 Recording vaccination

The individual should be given a record of vaccination and HSE advice leaflet for after vaccination. Vaccine administration should be recorded in the IT system.

Record the “USE BEFORE date and the batch number in the vaccination record (written on the vaccine box by the NCCS).

11.2 Observation period

Cases of anaphylaxis have been reported following administration of COVID-19 vaccines.

Please note that NIAC recommends a 15 minute observation period following administration of a homologous or heterologous booster COVID-19 mRNA vaccine.

Recommended observation period following vaccination (includes booster vaccination):

- All vaccine recipients (see exceptions below): 15 minutes of observation
- Those with a history of mastocytosis: 30 minutes
- Those with immediate itching, swelling or urticarial reaction at the vaccination site: 30 minutes or longer as clinically indicated

Vaccine recipients should be advised to seek urgent medical attention if they have symptoms suggestive of an allergic reaction such as difficulty breathing, feeling faint, rapid heartbeat or a skin rash.

12. Adverse Reactions

12.1 Adverse reactions of COVID-19 vaccines

Please refer to the relevant Summary of Product Characteristics for further details.

The adverse events are listed below in Table 8 according to the following frequency: Very common ($\geq 1/10$), Common ($\geq 1/100$ to $< 1/10$), Uncommon ($\geq 1/1,000$ to $< 1/100$), Rare ($\geq 1/10,000$ to $< 1/1,000$), Very rare ($< 1/10,000$).

Table 8: Adverse reactions of COVID-19 vaccines from clinical trials and post authorisation experience

Type of Reaction	Comirnaty® (Pfizer BioNTech)	Nuvaxovid® (Novavax)
Very Common ($\geq 1/10$)	Local: injection site pain, injection site swelling	Local: Injection site tenderness, Injection site pain
	General: arthralgia, fatigue, fever, chills, headache, myalgia, diarrhea	General: headache, nausea or vomiting, myalgia, arthralgia, fatigue, malaise
Common ($\geq 1/100$ to $< 1/10$)	Local: injection site erythema	Local: Injection site redness, Injection site swelling
	General: nausea, vomiting, lymphadenopathy***	General: pyrexia, pain in extremity
Uncommon ($\geq 1/1,000$ to $< 1/100$)	Local: injection site pruritus	Local: injection site pruritus
	General: insomnia, extremity pain (refers to the vaccinated arm), hyperhidrosis, night sweats, decreased appetite, asthenia, malaise, lethargy, hypersensitivity reactions (e.g. rash, pruritus, urticaria, angioedema), dizziness	General: Rash, Erythema, Pruritus, Urticaria, Hypertension* Lymphadenopathy Chills
Rare ($\geq 1/10,000$ to $< 1/1,000$)	General: acute peripheral facial paralysis	Injection site warmth
Very rare ($< 1/10,000$)	Myocarditis and pericarditis	
Not known (cannot be estimated from the available Data)	Anaphylaxis, Facial swelling in those who have had	Anaphylaxis, Paraesthesia, Hypoaesthesia, Myocarditis, Pericarditis

	dermatological fillers, Extensive swelling of the vaccinated limb, Erythema Multiforme, Paraesthesia and hypoesthesia, Heavy menstrual bleeding**	
<p>* Hypertension was not reported in adolescents aged 12 through 17 years in the clinical study. Throughout the clinical trials, an increased incidence of hypertension following vaccination with Nuvaxovid (n=46, 1.0%) as compared to placebo (n=22, 0.6%) was observed in older adults during the 3 days following vaccination.</p> <p>**Most cases appeared to be non-serious and temporary in nature</p> <p>*** In participants 5 years of age and older, a higher frequency of lymphadenopathy was reported after a booster ($\leq 2.8\%$) dose than after primary ($\leq 0.9\%$) doses of the vaccine.</p>		

- Events of anaphylaxis have been reported after COVID-19 vaccines. Appropriate medical treatment and supervision should always be readily available in case of an anaphylactic reaction following the administration of the vaccine
- Very rare events of neuroinflammatory disorders have been reported following vaccination with COVID-19 vaccines. A causal relationship has not been established

A higher rate of pyrexia (after Comirnaty®) was seen after the second dose compared to the first dose.

A higher rate of injection site reactions (redness, swelling, tenderness or pain), nausea or vomiting, myalgia, arthralgia, fatigue and malaise, and pyrexia were seen after the second dose of Nuvaxovid® (Novavax).

If required, symptomatic treatment with analgesic and/or anti-pyretic medicinal products (e.g. paracetamol containing products or ibuprofen) may be used. Note: Ibuprofen is not recommended for pregnant women.

12.2 Adverse events following Comirnaty® (Pfizer/BioNTech) and Spikevax® (Moderna) and very rare cases of Myocarditis and Pericarditis

There has been an increase of very rare cases of myocarditis and pericarditis following vaccination with both Comirnaty® and Spikevax.

The cases occurred particularly in males aged under 30 years, and following the second dose of Spikevax.

Reporting rates for vaccine-associated myocarditis were highest among males aged 12–29 years. In Israel, the estimated incidence 2 per 100,000 persons who had received at least one dose of Comirnaty®. The highest incidence of myocarditis was 10.7 per 100,000 in males aged 16-29 years. Most cases of myocarditis were mild or moderate in severity.

Studies have shown that after the second dose of Comirnaty® there were about 2.6 extra cases of myocarditis per 100,000 males aged 12 - 29 years after seven days and 5.7 extra cases of myocarditis per 100,000 males aged 16 - 24 years after 28 days. The rates for Spikevax were three to five times higher.

The risk is lower following booster vaccination. The risk of vaccine associated myocarditis can be reduced by extending the interval between the first and second mRNA COVID-19 vaccine dose in the primary schedule.

Healthcare professionals should be alert to the signs and symptoms of myocarditis and pericarditis. They should tell people receiving these vaccines to seek immediate medical attention if symptoms indicative of myocarditis or pericarditis occur. These include:

- breathlessness,
- palpitations and
- chest pain.

Healthcare professionals should consult applicable guidance and/or consult specialists (e.g. Cardiologists) to diagnose and treat these conditions.

12.3 Adverse events following Nuvaxovid® (Novavax) and unknown frequency of cases of Myocarditis and Pericarditis

There is an increased risk of myocarditis and pericarditis following vaccination with Nuvaxovid®. The safety of Nuvaxovid XBB.1.5 is inferred from the safety data of the Nuvaxovid® vaccine and the safety data from the adapted Omicron BA.5 vaccine.

These conditions can develop within a few days after vaccination and have primarily occurred within 14 days.

The EMA concluded that the overall risk benefit profile remains favourable.

Available data suggest that the course of myocarditis or pericarditis following vaccination is not different from myocarditis or pericarditis in general.

The frequency of myocarditis and pericarditis after Nuvaxovid® cannot be estimated from the available data.

Myocarditis and pericarditis may present with chest pain, shortness of breath, palpitations and fatigue. Most patients respond well to standard treatment, and the prognosis is good. However, it can occasionally progress to dilated cardiomyopathy and chronic heart failure.

Healthcare professionals should be aware of the signs and symptoms of myocarditis and pericarditis.

Vaccine recipients should be advised to promptly seek medical attention if they develop acute and persisting chest pain, palpitations or shortness of breath in the days after vaccination.

Healthcare professionals should consult applicable guidance and/or consult a Cardiologist for advice on management.

12.4 Reporting adverse reactions

The HPRA is responsible for managing the national pharmacovigilance system. The HPRA reports nationally occurring adverse reactions to the EMA.

Adverse reaction reporting is an important part of the EMA intensive monitoring plan for COVID-19 vaccines, so that any changes in benefit risk balance can be promptly detected and acted upon.

This enables the EMA to continue to safeguard public health safety.

COVID-19 vaccines are subject to additional monitoring. This will allow quick identification of new safety information.

Healthcare professionals and members of the public are encouraged to report any suspected adverse reactions to the HPRA following the instructions available on the HPRA website www.hpra.ie. As much information as is known should be provided, and where possible, the vaccine batch number should be included.

12.5 Reporting of incidents during the vaccination session to HSE

In the case of medication errors that directly involve the vaccine recipient, i.e. wrong medication/dose/route being administered or another medication error, the vaccinator must remain with the person and closely monitor them for any adverse reactions.

The incident must be reported to the relevant line manager/person in charge as soon as possible. The incident and all actions taken must be recorded and the relevant National Incident Management Report Form (NIRF) completed as soon as is practicable after the event occurs and within one working day. (National Incident Report Form (NIRF 01 – V12)) (2021) available at: <https://www.hse.ie/eng/about/qavd/incident-management/>

The vaccine recipient and/or significant others should be informed of the incident. An incident report form must be completed by the vaccinator and forwarded to local or regional Risk Manager as per local policy.

Any suspected adverse reactions associated with medication errors should be reported to the HPRA as outlined above.

13. **Guidance for vaccination of those who are contacts of a case of COVID-19**

If a person is required to restrict their movements, they must not attend for vaccination until the period of restricted movements has been completed. See <https://www.hpsc.ie/a-z/respiratory/coronavirus/novelcoronavirus/guidance/contacttracingguidance/>

Where vaccination is being carried out in Residential Care Facilities (residents and staff) the following advice applies:

Primary vaccination: asymptomatic close contacts of cases of COVID-19 may receive COVID-19 vaccine.

Asymptomatic individuals who have undergone testing for COVID-19 and who are residents in a long-term care facility should also proceed with vaccination while awaiting the results of their tests. Healthcare staff in LTCFs should follow all public health and occupational health guidance. www.hpsc.ie

Vaccination is a low contact clinical activity. Hand hygiene, PPE and infection prevention and control guidance should be followed. See www.hpsc.ie for details.



14. Vaccination of children aged 5-11 years

There are currently two COVID-19 vaccines available in age appropriate formulations for children aged 5-11 years in Ireland:

- **Comirnaty® Original/Omicron BA.4-5 10 micrograms (0.2ml)**
 - for primary course vaccination
 - may be used for booster vaccination if Comirnaty® Omicron XBB.1.5 for children aged 5-11 years is not available
- **Comirnaty® Omicron XBB.1.5 10 micrograms (0.2ml)**
 - for booster vaccination only
 - Comirnaty® Omicron XBB.1.5 is the preferred vaccine for booster vaccination, however if this vaccine is unavailable then Comirnaty® Original/Omicron BA.4-5 for children aged 5-11 years may be used as an alternate for booster vaccination.

Comirnaty® Original/Omicron BA.4-5 for children aged 5-11 years was first recommended for marketing authorisation by the European Medicines Agency on the 10th November 2022. It is an adapted vaccine which provides added protection against the BA.4 and BA.5 Omicron variants of COVID-19.

Comirnaty® Original/Omicron BA.4-5 10 micrograms (0.2ml) is licensed for active immunisation to prevent COVID-19 caused by SARS-CoV-2, in children aged 5-11 years who have previously received at least a primary vaccination course against COVID-19.

In December 2022, the EMA's Emergency Task Force concluded that Comirnaty® Original/Omicron BA.4-5 vaccines may be used in primary vaccination of previously unvaccinated children and adults.

Therefore, **Comirnaty® Original/Omicron BA.4-5 10 micrograms (0.2ml) for those aged 5-11** may be used for primary vaccination in previously unvaccinated children in this age group, and for an additional dose and booster vaccination.

When used as a primary course, the dose and schedule of Comirnaty® Original/Omicron BA.4-5 for this age group is 10 micrograms, two doses given 8 weeks apart (for immunocompromised children the two doses are recommended 4 weeks apart, see Table 1). A minimum interval of 3 weeks may be used if there is urgency to achieve protection.

Comirnaty® Omicron XBB.1.5 for children aged 5-11 years was recommended for authorisation by the [European Medicines Agency on 30th August 2023](#). In its decision to recommend the authorisation, the EMA's Committee for Medicinal Products for Human Use (CHMP) considered all the available data on Comirnaty® and its other adapted vaccines, including data on safety, efficacy and immunogenicity. In addition, the Committee assessed new laboratory data showing a strong response of the adapted vaccine against XBB.1.5 and related strains of the virus that causes COVID-19.

Comirnaty® Omicron XBB.1.5 10 micrograms (0.2ml) is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2, in children aged 5 to 11 years. It should be used for booster vaccination only.

The National Immunisation Advisory Committee (NIAC) recommends the preferential use of Comirnaty® Omicron XBB.1.5 10 micrograms (0.2ml) for booster vaccination of children aged 5-11 years when it becomes available in Ireland. In the interim, Comirnaty® Original/Omicron BA.4-5 10 micrograms (0.2ml) should continue to be used.

14.1 NIAC recommendation

Following approval of the original Comirnaty® 10 micrograms (0.2ml) formulation for children aged 5-11 years by the EMA in November 2021, the NIAC has made the following recommendations:

- A primary course of COVID-19 vaccination is recommended for those aged 5 to 11 years:
 - With underlying conditions
 - Living with a younger child with complex medical needs
 - Living with a person who is immunocompromised
- COVID-19 vaccination should be offered to all other children aged 5 to 11 years
 - This is because of the favourable benefit risk profile of the vaccine, to protect them from severe disease and from the consequences that can follow infection e.g., multisystem inflammatory syndrome in children (MIS-C), long COVID as well as psychosocial and developmental impacts.
- Children aged 5 to 11 years who are severely immunocompromised should be given a third dose of Comirnaty® 8 weeks after the second dose to complete the primary series (a minimal interval of 4 weeks between the second and third dose may be used if there is urgency to achieve protection).

Before vaccination, parents or guardians should be informed of the known benefits, risks and uncertainties of COVID-19 vaccination.

14.2 Formulations for booster vaccination of those aged 5-11 years

- i) Comirnaty® Omicron XBB.1.5 10 micrograms (0.2ml) – preferred booster vaccine if available
- ii) Comirnaty® Original/Omicron BA.4-5 10 micrograms (0.2ml)

Recommendations for booster vaccination of those aged 5-11 years

A first mRNA COVID-19 booster vaccine is recommended for those aged 5 – 11 years with immunocompromise associated with a sub optimal response to vaccines at the time of their primary or additional vaccination (See Table 5a.2 areas shaded in blue).

A **first booster** dose of Comirnaty® Omicron XBB.1.5 10 micrograms (0.2ml) or Comirnaty® Original/Omicron BA.4-5 10 micrograms (0.2ml) should be given to all those aged 5-11 years with immunocompromise associated with a suboptimal response to vaccines who have completed an extended primary vaccination course (three doses) after an interval of **4 months**.

In exceptional circumstances an interval of 3 months may be used (e.g., in a person scheduled to commence chemotherapy).

Children who have become immunocompromised since completing their primary vaccination course are expected to have mounted an adequate response to their primary vaccination. They do not require an additional dose (extended primary series). A first booster dose is recommended 4 months after completion of their primary course.

Children aged 5-11 years with immunocompromise associated with a sub-optimal response to vaccination are recommended to receive further COVID-19 booster vaccines in both Spring and Autumn 2023 (see Table 1). Children aged 5-11 years with an underlying medical condition associated with a higher risk of COVID-19 hospitalisation, severe disease, or death are recommended to receive a booster vaccine in Autumn 2023 (see Table 1).

For healthy children aged under 12 years COVID-19 booster vaccination is not recommended.

Recommended intervals for Spring and Autumn booster vaccinations 2023:

- For those aged 5-11 years with immunocompromise associated with a sub-optimal response to vaccination, an interval of **6 months** is recommended following any previous COVID-19 vaccine dose or SARS-CoV-2 infection.
- For those aged 5-11 years with medical conditions associated with a higher risk of COVID-19 hospitalisation, severe disease or death, for whom a COVID-19 booster vaccine in Autumn 2023 is recommended, an interval of **9 months** from previous COVID-19 vaccine dose or SARS-CoV-2 infection is recommended.
- Healthy children aged 5-11 years are not recommended a booster vaccine in either Spring or Autumn 2023.

For more information on the recommended intervals for Spring and Autumn boosters for eligible children aged 5-11 years, please see Table 1.

The decision to accept, defer or refuse vaccination for a child should be respected.

14.3 Vaccine storage for Comirnaty® formulations for those aged 5-11 years

The following is applicable to both formulations (Comirnaty® Original/Omicron BA.4-5 10 micrograms (0.2ml) and Comirnaty® Omicron XBB.1.5 10 micrograms (0.2ml) :

- The vaccine is delivered from the manufacturer to the HSE NCCS at -90°C to -60°C and this storage condition is continued as the vaccine is stored in an ULT freezer at - 90°C to -60°C.
- The vaccine is supplied to sites/clinics by the HSE NCCS at +2 to +8°C with a shelf life of up to 10 weeks. This new “use before” time and date is labelled by NCCS once vials are removed from ULT.
- The vaccine in each multi-dose vial requires dilution with 1.3ml of 0.9% sodium chloride.
- 0.9% sodium chloride is supplied separately to the vaccine and should be stored at room temperature.
- Undiluted vials of Comirnaty® (Pfizer/BioNTech) have a shelf life of 10 weeks when stored at +2 to +8°C (labelled “use before” time and date) and up to 12 hours at up to +30°C.
- After dilution, the vaccine must be kept at +2°C to +30°C and used within 12 hours after which the vial must be discarded.

Summary of Comirnaty® Original/Omicron BA.4-5– for children aged 5 to 11 years

Title	Description
Name of vaccine	Comirnaty Original/Omicron BA.4-5 (5/5 micrograms)/dose concentrate for dispersion for injection
Constituents	((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) (ALC-0315) 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-0159) 1,2-Distearoyl-sn-glycero-3-phosphocholine (DSPC) Cholesterol Trometamol Trometamol hydrochloride Sucrose Water for injections
Number of doses in each vial	10 doses per vial after dilution. If more than 10 doses can be accurately withdrawn from a diluted vial, it is a valid dose. No more than 12 valid doses are available.
Dilution	Yes dilute with 1.3mls of 0.9% Sodium Chloride (supplied separately)
Dosage	0.2ml
Latex	No
Preservatives	No

Summary of Comirnaty® Omicron XBB.1.5 for children aged 5 to 11 years

Title	Description
Name of vaccine	Comirnaty® Omicron XBB.1.5 10 micrograms/dose concentrate for dispersion for injection
Constituents	((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) (ALC-0315) 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-0159) 1,2-Distearoyl-sn-glycero-3-phosphocholine (DSPC) Cholesterol Trometamol Trometamol hydrochloride Sucrose Water for injections
Number of doses in each vial	10 doses per vial after dilution. If more than 10 doses can be accurately withdrawn from a diluted vial, it is a valid dose. No more than 12 valid doses are available.
Dilution	Yes dilute with 1.3mls of 0.9% Sodium Chloride (supplied separately)
Dosage	0.2ml
Latex	No
Preservatives	No

14.4 Vaccine dose (for both Comirnaty® Omicron XBB.1.5 and Comirnaty® Original/Omicron BA.4-5 for children aged 5-11 years)

The vaccine for children is a different vaccine formulation, it contains a lower dose of antigen (10 micrograms per dose). The dose of the diluted Comirnaty® for children 5-11 years vaccine is **0.2ml**.

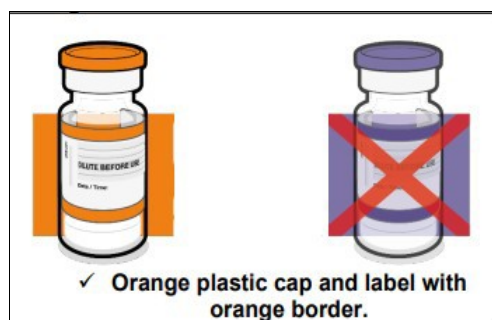
Dosage of Comirnaty® Original/Omicron BA.4-5 10 micrograms (0.2ml) when used for primary vaccination

Two doses of Comirnaty® Original/Omicron BA.4-5 10 micrograms/dose for children aged 5-11 years are required for primary vaccination.

The dose of Comirnaty® Original/Omicron BA.4-5 depends on the age at the time of vaccination i.e., an 11-year-old child who receives the first dose of 10 micrograms Comirnaty® Original/Omicron BA.4-5 and who is 12 years of age at the time of their second dose, should receive the 30 microgram dose of Comirnaty® Original/Omicron BA.4-5 as a second dose.

This is a different dose compared to the dose for those aged ≥ 12 years.

This image shows the children's formulation (5-11 years)



14.5 Interval between doses (of Comirnaty® Original/Omicron BA.4-5 10 micrograms (0.2ml) when used for primary vaccination of children aged 5-11 years)

The recommended interval between doses is **8 weeks⁵** (for immunocompromised children the recommended interval between dose one and dose two is **4 weeks**).

If the interval between doses is longer than the recommended interval, the second dose should be given as soon as possible. The course does not need to be restarted.

If the second dose is given more than four days before the minimum interval, this is not considered a valid dose. A third dose should be given at least eight weeks after the second (invalid) dose. A **minimum interval of 21 days** may be used if there is urgency to achieve protection. For those who are immunocompromised a third dose should be given at least four weeks after the second (invalid) dose.

An additional dose of Comirnaty® Original/Omicron BA.4-5 10 micrograms (0.2ml) as part of an extended primary series should be given to those aged 5-11 years with immunocompromise, see Table 1.

⁵Note that the day the first dose of vaccine is given is day 0

Interval between 1st and 2nd Doses	Action required
Less than 17 days	This is not considered a valid dose. A third dose should be given at least 8 weeks after the second (invalid) dose. A minimum interval of 21 days may be used if there is urgency to achieve protection. For those who are immunocompromised a third dose should be given at least 4 weeks after the second (invalid) dose.
17 days to 8 weeks (4 weeks for immunocompromised children)	No further action needed. This is a valid dose.
Longer than 8 weeks (Longer than 4 weeks for immunocompromised children)	Give the second dose as soon as possible. The course does not need to be restarted.

Prior to vaccination

- Check valid consent has been obtained
- Check for contraindications or precautions
 - See later in this chapter and the NIAC Immunisation guidelines for COVID-19 available at <https://www.rcpi.ie/healthcare-leadership/niac/immunisation-guidelines-for-ireland>
- Vaccinators who are vaccinating using a medicines protocol should check vaccine recipient's eligibility under the protocol
- Check the interval when administering a second dose
- Explain the procedure
- Answer questions
- Maintain privacy & dignity

14.6 Infection prevention and control

- Prior to preparation and administration of COVID-19 vaccines, hand hygiene should be performed as per the "WHO five moments of hand hygiene" with emphasis on:
 - Before vaccine preparation
 - Before drawing up and administering the vaccine
 - Before and after each recipient contact
 - PPE should be worn as per HPSC guidance for healthcare staff.
 - It is not necessary to use a skin disinfectant prior to injection. If the skin at the injection site is visibly dirty, clean with soap and water. If an alcohol swab is used, delay injection for ≥30 seconds, to ensure the alcohol has evaporated.
 - Gloves are not routinely recommended for vaccine preparation and administration
 - There is no need to routinely check temperature either at registration or before vaccination.
 - Follow HPSC standard precautions (sharps management, healthcare waste management etc.)
- National Clinical Guideline No. 30 (2023) – Infection Prevention and Control (IPC)
<https://www.gov.ie/en/publication/a057e-infection-prevention-and-control-ipc/>.

- Check HPSC website for latest guidance on infection prevention and control for healthcare workers:

National Clinical Guideline No. 30 (2023) – Infection Prevention and Control (IPC)

<https://www.gov.ie/en/publication/a057e-infection-prevention-and-control-ipc/>.

14.7 Vaccine, Preparation and Dilution

Note: Dilution, labelling and administration for Comirnaty® Original/Omicron BA.4-5 and Comirnaty® Omicron XBB.1.5 used for children aged 5-11 years are same.

Prior to dilution

- Perform hand hygiene
- Check you are using the correct formulation
- Verify that the vial has an orange plastic cap and the product name is:
Comirnaty® Original/Omicron BA.4-5 (5/5 micrograms)/dose concentrate for dispersion for injection
OR
- Comirnaty® Omicron XBB.1.5 10 micrograms/dose concentrate for dispersion for injection.

Preparation for dilution

Prepare the equipment needed for dilution:

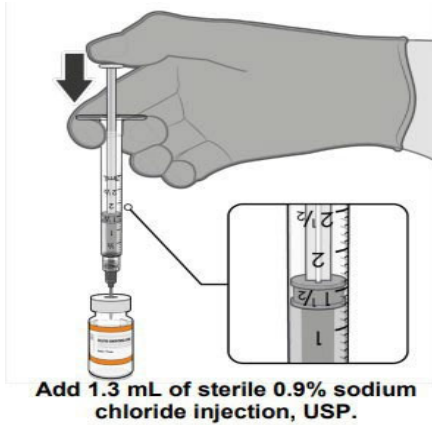
- A clean tray
- One multidose vial of Comirnaty® for 5-11 years.
- One plastic ampoule of Sodium Chloride 0.9% Solution for Injection
- This should not be kept in the fridge
- A needle and a syringe to dilute
- Needles and syringes will be supplied
- Two 70% alcohol swabs

Check the **use before date and time** on the box containing the vials. Before dilution mix by inverting vaccine vial gently 10 times, do not shake. Inspect the liquid in the vial prior to dilution, the liquid is a white to off-white suspension and may contain opaque amorphous particles. Do not use if the liquid is discoloured or if other particles are observed.

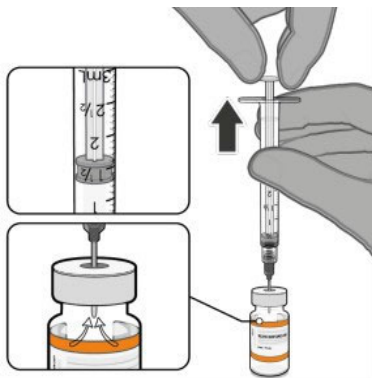
Dilution

- Take one ampoule of sodium chloride and check expiry date.
- Clean with 70% alcohol swab
- Open the ampoule by twisting the cap
- Connect the syringe tightly (No needle is required)
- Follow Aseptic technique
- Do not touch the key parts of the ampoule & syringe
- Withdraw 1.3 ml of Sodium Chloride 0.9% Solution for Injection
- Cross check with colleague
- Discard the ampoule and any remaining diluent in it
- Attach needle to the syringe
- Insert diluent into the vaccine vial

- You may feel some pressure in the vial as you add the diluent



- Do not remove the needle and syringe from the vial until you have equalised the vial pressure by slowly withdrawing 1.3 ml of air into the empty diluent syringe before removing the needle from the vial



Pull back plunger to 1.3 mL to remove air from vial.

- Gently invert the diluted solution 10 times, do not shake



Gently × 10

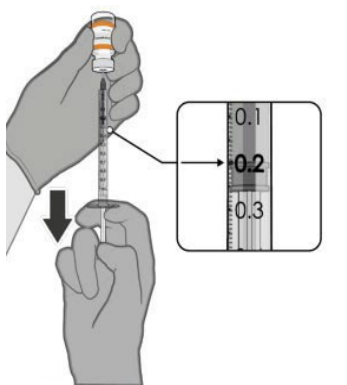
- Inspect the vial
- The diluted vaccine should be an off-white suspension
- Do not use if vaccine is discoloured or contains particulate matter

Labelling the diluted vial

- Label the diluted vial with the discard time and date (12 hours after time of dilution) using a 24-hour format. Do not use it after this time and date
e.g., time of dilution was 08.00 20/09/2023. The discard time and date is 20.00 20//09/2023
- After dilution, the vial contains 2.6 ml from which 10 doses of 0.2ml can be extracted
 - **The volume of each dose is smaller than the adult dose**
- Diluted vaccines can be stored between +2°C and +30°C but must be used within 12 hours following dilution
- Bring the vial to your vaccination table/site.

Vaccine Dose Preparation

- Check that the time of vaccine dilution was within the last 12 hours
- Perform hand hygiene
- Clean top of vial with a single use 70% alcohol swab and allow it to air dry fully
- Attach 23 gauge / 25 gauge in size and 25mm in length needle to 1ml syringe
- The needle size is the same as for those aged 12 years and older
- Withdraw **0.2 ml** of diluted product



Withdraw 0.2 mL dose of vaccine.

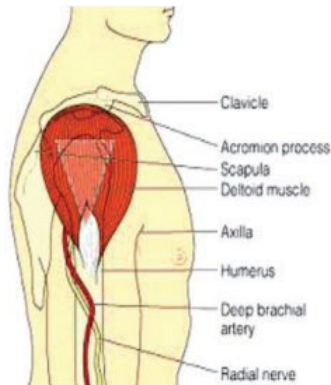
- Make sure correct dose is drawn up as smaller dose may not provide protection
- Before the needle is withdrawn ensure all air bubbles have been removed
- Do not change the needle between the vial and the patient unless the needle is contaminated or damaged.

14.8 Vaccine Administration of Comirnaty® for 5-11 years.

- Administer vaccine to patient intramuscularly, into the deltoid muscle
- Dispose the syringe and the needle into the sharps bin
- If more than ten 0.2ml doses can be safely and accurately withdrawn from a diluted vial, they can be used as valid doses
- There is a **maximum of 12 doses** in each vial
- Do not leave the empty vials unattended
- Dispose the empty vials safely into a sharps bin
- Low dead space syringes should be used if available in order to maximise the number of doses that can be drawn from the vial
- **There should be no pooling of vaccine** solution from different vials.

14.9 Method of IM Vaccine Administration

- Intramuscular injection technique for children aged 5-11 is the same as for older children and adults
- Vaccine to be given Intramuscularly into the deltoid muscle
- The light triangle in figure indicates site for IM injection into the deltoid muscle

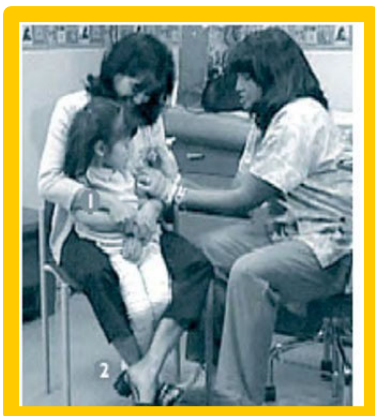


- The upper border of the triangle is approximately two finger-breadths below the acromion process and the apex is at the midpoint of the humerus
- The needle size for IM injection is the same as that for adults (23 gauge / 25 gauge in size and 25mm in length needle)
- At the injection site spread the skin taut between the thumb and forefinger with the non- dominant hand
- Do not bunch up the skin as this leads to administering the vaccine into subcutaneous tissue inadvertently
- Further information is available at www.immunisation.ie

14.10 Positioning for vaccination

For younger/smaller children:

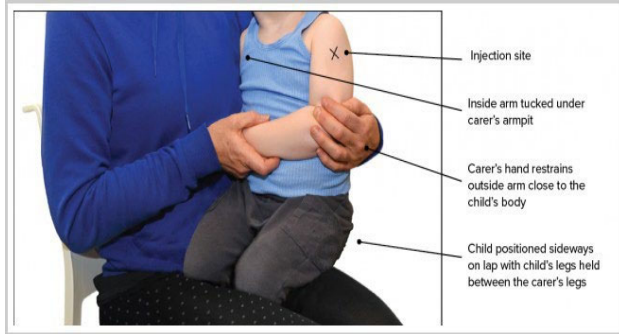
- The child sits on the parent/carer's lap or stands in front of them as they sit
- The parent/carer embraces the child during the process, holding both the child's arms as they do so both of the child's legs are anchored between the parent/carer's thighs



Source: Immunisation guidelines of the NIAC

Alternative positioning

- Sit child facing to the side. One arm is tucked under the parent/carer's armpit (A cuddle position)



Source: Australian Immunisation handbook

For older/bigger children

- It may be appropriate to ask the parent/carer and the child the preferred sitting position for vaccine administration
- They may prefer to sit on the parent/carer's lap or to sit independently

14.11 Techniques for vaccinating children

- Be honest and calm. Take time to explain in simple terms what to expect. Explain that the child may feel a little pinch and it will go away very quickly.
- Use words like “pressure” or “pinch” rather than “pain” or “shot”
- Distraction techniques can help in reducing pain and anxiety during vaccination. Keep the distraction going after the vaccine is given
 - Looking at toys, books, etc.
 - Pointing out interesting things in the room
 - Telling or reading stories
 - Taking deep breaths to help “blow out” the pain
 - Counting to five backwards

What to do if the child does not want to be vaccinated

- Only one person should hold the child for vaccination at any time (to avoid risk of needle stick injury)
- If the child cannot be held/positioned by the parent/carer so that vaccination is possible, then the child should not be vaccinated
- Repeated attempts to vaccinate the child are unlikely to help
- Check with your clinical lead for advice
- It may be better to bring the child back another time
- With the parent if parent was not present.
- They may benefit from vaccination during quiet times

Prevention and Management of Syncope in Vaccination Clinics

- Syncope is rare in younger children, it is more common in adolescents
- Syncope episodes mostly occur within 15 minutes of vaccine administration
- Reassurance about the procedure may help to prevent fainting
- Recipients should be seated (or lying down - if past history of fainting) when being administered their vaccines in case of an immediate faint
- There should be facilities in place in case of fainting
 - So that the person can be placed in a recumbent position/lie down or sit with head between knees

for several minutes if lying down is not possible

- It may be helpful to loosen any tight clothing and apply cool, damp cloths to the person's face and neck
- Further information is available on the www.immunisation.ie and at <https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/>

14.12 Contraindications and precautions to COVID-19 vaccination in children aged 5-11 years for Comirnaty® Original/Omicron BA.4-5 10 micrograms (0.2ml) and for Comirnaty® Omicron XBB.1.5 10 micrograms (0.2ml)

Contraindications

- Anaphylaxis (serious systemic allergic reaction requiring medical intervention) following a previous dose of the vaccine or any of its constituents (including polyethylene glycol (PEG) and trometamol).
- Anaphylaxis after an mRNA vaccine

Appropriate support should be available in case of anaphylaxis or fainting after vaccine administration. Precautions should be in place to minimise injury from fainting

Precautions:

- Acute severe illness; defer until recovery
- Previous history of myocarditis or pericarditis after any COVID-19 vaccine – seek specialist advice (i.e. consult with a Cardiologist)
- **Vaccination should be postponed in children with a previous history of MIS-C, until clinical recovery or until 90 days or more since diagnosis, whichever is the longer.**
- There should be an interval of at least 4 weeks between mpox/smallpox vaccine and a subsequent COVID-19 vaccine because of the unknown risk of myocarditis.

If vaccination is advised for a child with prior history of mastocytosis, observe for 30 minutes after vaccination.

For full list of contraindications and precautions see **Table 5a.3 of the NIAC Immunisation Guidelines for Ireland.**

The following are **not contraindications or precautions** to vaccination:

- Food allergy (non-anaphylactic)
- Family history of allergy, including anaphylaxis
- Previous local reaction to any vaccine
- Underlying asthma
- Hay fever
- Hereditary angioedema
- Contact dermatitis to PEG containing cosmetic product
- NSAID allergy
- Chronic spontaneous urticaria

14.13 Post-vaccination Procedures

Documentation post vaccination

- Record vaccine batch number in the record/IT system
 - It will automatically link to the expiry date, so there is no need to record the expiry date
- Boxes delivered by NCCS will be labelled with a Use before date and time
- This use before date and time should be recorded in the patient record**
- Give record card to vaccinee or parent/guardian
- Give post vaccination information sheet to vaccinee or parent/guardian

Observation post-vaccination

- Vaccine recipients: 15 minutes of observation
- Those with a history of mastocytosis: 30 minutes of observation
- Those with immediate itching, swelling or urticarial reaction at the vaccination site: 30 minutes or longer as clinically indicated

Advice following vaccination

- Give the parent/carer the after-care leaflet information
- Parent/carer should be advised that COVID-19 vaccines may cause a fever which usually resolves within 48 hours. This is a common, expected reaction and isolation and further investigation is not required unless COVID-19 is suspected
- If fever lasts for > 48 hours, or if other symptoms of COVID-19 are present, the person should self-isolate and seek medical advice
- Paracetamol or ibuprofen can be taken after vaccination if the child develops pain, fever or myalgia
- Advise the child's parent/carer that vaccinated children may still get infected and transmit the virus so they should continue to follow all current public health guidance to protect themselves and others
- Please refer to the NIAC immunisation guidelines available at <https://www.rcpi.ie/healthcare-leadership/niac/immunisation-guidelines-for-ireland>

14.14 Adverse Events

Adverse Events - Comirnaty® Original/Omicron BA.4-5 10 micrograms (0.2ml) for those aged 5-11 years

The safety of a booster dose of Comirnaty® Original/Omicron BA.4-5 is inferred from safety data for a booster dose of an Omicron BA.1 adapted vaccine, as well as for a booster dose of Comirnaty® Original.

Common adverse events following administration of Comirnaty® Original/Omicron BA.4-5 are listed below, a full list of adverse reactions may be found in the Summary of Product Characteristics (SmPC).

Local:	Very common: injection site pain, swelling Common: injection site redness
General:	Very common: arthralgia, chills, diarrhoea, fatigue, headache, myalgia, pyrexia Common: nausea, vomiting

Adverse Events - Comirnaty® Omicron XBB.1.5 10 micrograms (0.2ml) for those aged 5-11 years

The safety of Comirnaty® Omicron XBB.1.5 is inferred from safety data of the prior Comirnaty® vaccine.

Myocarditis and pericarditis

Myocarditis and pericarditis are inflammatory conditions of the heart. Symptoms can vary but often include breathlessness, palpitations and chest pain. An EMA review listed Pericarditis and Myocarditis as a **very rare** side effect of Comirnaty® vaccine. The risk is highest in younger males and is more often observed after the second dose. Two European studies have estimated the risk of myocarditis after the second dose of the vaccine:

- One additional case for every 38,000 men aged 12 to 29 (within 7 days)
- One additional case for every 17,500 men aged 16-24 (within 28 days)

Data are very limited on those 5 to 11 years of age.

Myocarditis has also been associated with COVID-19 infection and these events can also occur in all age groups unrelated to vaccines or to COVID-19. Available data suggest that the course of myocarditis and pericarditis following vaccination is similar to the typical course of these conditions and in most individuals, symptoms resolved with conservative management. The long-term follow-up of these cases is ongoing.

Reporting of adverse events following immunisation

Adverse Events Following Immunisation should be reported to the HPRA:

<https://www.hpra.ie/homepage/about-us/report-an-issue/human-adverse-reaction-form>

14.15 Clinical considerations

Vaccination after COVID-19 infection

Unvaccinated

Those who are unvaccinated and develop SARS-CoV-2 infection should complete a primary vaccination course, with the first dose at least four weeks after diagnosis or onset of symptoms, or four weeks from the first PCR positive specimen in those who are asymptomatic.

Those with persisting symptoms following COVID-19 may be vaccinated, unless there is evidence of recent clinical deterioration.

Partially vaccinated

Those who have had SARS-CoV-2 infection after their first dose of COVID-19 vaccine should be given the subsequent dose at least eight weeks after diagnosis or onset of symptoms.

If those who are immunocompromised have SARS-CoV-2 infection more than seven days after the second vaccine dose, a third dose of the primary series is not required. They should proceed to their first booster dose as per Table 1 (or Table 5a.1 of the NIAC Immunisation Guidelines for Ireland).

For those with infection within seven days of their second dose they should complete the extended primary series after an interval of 4-8 weeks.

Booster vaccination

Those children who have had SARS-CoV-2 infection after completing their primary series (i.e., a breakthrough infection), should proceed to booster vaccination if eligible as recommended in Table 1.

Co-administration with other vaccines

COVID-19 vaccine may be given at the same time or at any interval as other vaccines (live and non-live) including influenza vaccine and the vaccines administered in the school immunisations programme. The only exception to this is children who have received mpox (formerly known as monkeypox) vaccine. In this instance, there should be at least a 4 week interval between mpox vaccine and a subsequent COVID-19 vaccine.

Children who are immunocompromised

Children who are immunocompromised due to disease or treatment may be vaccinated if they have no contraindications. Data indicates that those with severe immunocompromise do not have adequate protection following a primary COVID-19 vaccine course. There is evidence that protection can be enhanced by an additional mRNA vaccine dose, representing an extension of the primary vaccination series. See Table 5a.2 of the NIAC guidelines for conditions that may be associated with a suboptimal response to vaccines.

An additional dose of Comirnaty® Original/Omicron BA.4-5 10 micrograms (0.2ml) should be given to those aged 5-11 years with immunocompromise associated with a suboptimal response to vaccines at the time of vaccination, who have completed their primary course. This is an extended primary vaccination course.

Children who are severely immunocompromised at the time of vaccination can have the additional (3rd dose) 8 weeks after the second dose (a minimal interval of 4 four weeks between the second and third dose may be used if there is urgency to achieve protection).

Children with planned immunosuppressing therapy should ideally complete vaccination two weeks before treatment. The recommended minimum interval may be used. Specialists should consider the child's risk and likelihood of disease exposure, and provide advice based on knowledge and understanding of their immune status and likely immune response to vaccination.

Booster vaccination of children who are immunocompromised

A booster dose is recommended for children aged 5 – 11 years with immunocompromise associated with a sub optimal response to vaccines at the time of their primary vaccination.

A booster dose is also recommended in children who have become immunocompromised following their primary vaccination course.

A first booster dose of Comirnaty® Omicron XBB.1.5 10 micrograms (0.2ml) (or Comirnaty® Original/Omicron BA.4-5 10 micrograms (0.2ml) if Comirnaty® Omicron XBB.1.5 10 micrograms (0.2ml) is unavailable) is recommended at least 4 months after the last vaccine dose. In exceptional circumstances, a 3 month interval may be used (see Table 1).

In individuals who have had a laboratory-confirmed /antigen positive with symptoms breakthrough infection following their last dose of vaccine of the primary vaccination series, the first booster dose should be delayed for at least 4 months. In exceptional circumstances a 3 month interval may be used.

Children aged 5-11 years with immunocompromise associated with a sub-optimal response to vaccination are recommended to receive further COVID-19 booster vaccines in both Spring and Autumn 2023. Children aged 5-11 years with an underlying medical condition associated with a higher risk of COVID-19 hospitalisation, severe disease, or death are recommended to receive a booster vaccine in Autumn 2023.

For information on recommended intervals for Spring and Autumn boosters for eligible children aged 5-11 years, please see Table 1.

Vaccination of those with bleeding disorders or on anticoagulants

Individuals with a bleeding disorder or receiving anticoagulant therapy may develop haematomas in IM injection sites. Prior to vaccination, inform the parent or guardian about this risk.

For those with thrombocytopenia (platelet count $<50 \times 10^9$ /L consult the supervising consultant. People with mild bleeding disorders or on maintenance dose Efficizumab (Hemlibra) do not require haemostatic cover for vaccination.

Those with inherited coagulopathies who require factor replacement therapy should receive it on the day of vaccination, prior to the IM vaccination. If there is uncertainty about the need for replacement therapy, contact the child's supervising consultant.

Those receiving long-term anticoagulation with either Warfarin or heparin are not considered to be at higher risk of bleeding complications following vaccination. There is no reason to expect that there is a greater risk of bleeding complications with the oral anticoagulants or antiplatelet agents, than with other anticoagulants.

See Chapter 2 of the NIAC guidelines, sections 2.4.6 and 2.4.7 for further information, including technique for IM injection, in this patient group.

15. Vaccination of Children Aged 6 months to 4 years:

Comirnaty® 3 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION (INFANTS AND CHILDREN 6 MONTHS TO 4 YEARS)

For children aged 6 months to 4 years, the recommended COVID-19 vaccine is Comirnaty® 3 micrograms.

Comirnaty® 3 micrograms is licensed for active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus in children aged 6 months to 4 years.

The dose of Comirnaty® for children aged 6 months to 4 years is 3 micrograms (0.2ml). The primary course for all children in this age group is three doses with an interval of 3 weeks between dose one and two, and an interval of 8 weeks between dose two and three.

15.1 NIAC Recommendation

Following the approval of Comirnaty® by the EMA for children aged 6 months to 4 years in October 2022, NIAC has made the following recommendations:

A primary course of COVID-19 vaccination is **recommended** for those aged 6 months-4 years with underlying conditions that place them at higher risk of severe COVID-19.

COVID-19 vaccination should be offered to all others aged 6 months-4 years because of:

- the protection provided against severe COVID-19 and Multisystem Inflammatory Syndrome in Children (MIS-C) and their late consequences
- the enhanced protection vaccination gives to those who have had COVID-19 infection
- the modest protection for reducing transmission to household contacts e.g. immunocompromised and those too young for vaccination.
- the safety profile of the vaccines
- similar vaccine immunogenicity to that in older children and adolescents.

Before vaccination, parents/guardians should be informed of the known benefits, risks, and uncertainties of COVID-19 vaccination.

Booster dose

Currently, the recommendation for vaccination in this age group is a primary course of three doses of Comirnaty® 3 micrograms (see Table 1 of this document). There is currently no recommendation for additional doses or boosters in this age group, regardless of whether immunocompromise is present.

The decision to accept, defer, or refuse vaccination for a child should be respected.

15.2 Vaccine storage

- From delivery by the manufacturer to the NCCS the vaccine is stored at -90°C to -60°C.
- The vaccine is supplied to sites/clinics by the NCCS at +2°C to +8°C with a shelf life of up to 10 weeks. Vials should be stored in pharmaceutical fridge between +2°C to +8°C. The new “use before” date and time is on the “HSE Scan me label” which has been affixed by the NCCS once vials are removed from ULT freezer. Do not refreeze vials. The vaccine in each multi-dose vial requires dilution with 2.2ml of 0.9% sodium chloride.
- 0.9% sodium chloride is supplied separately to the vaccine and should be stored at room temperature.
- Undiluted vials of Comirnaty® 6 months to 4 years (Maroon Cap) have a shelf life of up to 10 weeks. Prior to use, the unopened vials can be stored for up to 12 hours at temperatures between +8 °C and +30 °C.
- After dilution, the vaccine must be kept at +2°C to +30°C and used within 12 hours, after which the vial must be discarded.

Summary of Comirnaty® 3 micrograms/dose

Title	Description
Name of vaccine	Comirnaty® 3 micrograms/dose concentrate for dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified)
Constituents	((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) (ALC-0315) 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-0159) 1,2-Distearoyl-sn-glycero-3-phosphocholine (DSPC) Cholesterol Trometamol Trometamol hydrochloride Sucrose Water for injections
Number of doses in each vial	Post-dilution 10 doses If more than 10 doses can be accurately withdrawn from a diluted vial, it is a valid dose. No more than 12 doses are available.
Dilution	Yes, dilute with 0.9% sodium chloride (supplied separately).
Latex	The vial stopper does not contain latex.
Preservatives	No
Dosage	0.2ml
Number of doses required	3
Interval between doses	The recommended interval is 3 weeks between dose one and two and an interval of 8 weeks between dose two and three.

15.3 Vaccine dose

The vaccine for children aged 6 months to 4 years contains a lower dose of antigen (3 micrograms per dose) than for other age groups. The dose of the diluted vaccine is 0.2ml. Three doses of Comirnaty® 3 micrograms (0.2ml) are required for full protection in children aged 6 months to 4 years.

The dose of Comirnaty® depends on the age at the time of the vaccination e.g., a 4 year old child should receive the first dose of Comirnaty® 3 micrograms (0.2ml) and if they have turned 5 years of age at the time of a subsequent dose, the dose given should be Comirnaty® Original/Omicron BA.4-5 10 micrograms.

Therefore, if a child becomes five years of age before completion of the recommended course, the schedule should be completed with the age appropriate dose, Comirnaty® Original/Omicron BA.4-5 10 microgram as follows:

- If they have received one dose of Comirnaty® 3 micrograms: leave an interval of 3 weeks, then give two doses of Comirnaty® Original/Omicron BA.4-5 10 micrograms 8 weeks apart
- If they have received two doses of Comirnaty® 3 micrograms: leave an interval of 8 weeks, then give one dose of Comirnaty® Original/Omicron BA.4-5 10 micrograms

Interval between doses

The date of administration of the first dose is to be calculated as Day 0.

If the interval between doses is longer than the recommended interval, the next dose should be given as soon as possible. The course does not need to be restarted.

If the second dose is given more than four days before the minimum interval this is not considered a valid dose. A further dose should be given at least eight weeks after the invalid dose.

If the third dose is given more than four days before the minimum interval this is not a valid dose. A minimum interval of 21 days may be used if there is urgency to achieve protection. A further dose should be given at least eight weeks after the invalid dose.

Interval between 1 st and 2 nd doses	Action required
Less than 17 days	This is not considered a valid vaccine. Another dose should be given at least 8 weeks after the invalid vaccine. The third valid dose should then be given a further 8 weeks after the second valid dose.
Between 17 to 21 days	No further action needed (this is a valid vaccine).
Longer than 3 weeks/21 days	Give the second dose as soon as possible. The course does not need to be restarted.

Interval between 2 nd and 3 rd doses	Action required
Less than 17 days	This is not considered a valid vaccine. Another dose should be given at least 8 weeks after the invalid vaccine to complete the primary course.
Between 17 to 56 days	No further action needed (this is a valid

	vaccine).
Longer than 8 weeks/56 days	Give the third dose as soon as possible. The course does not need to be restarted.

15.4 Prior to vaccination

- Check valid consent has been obtained from a parent of legal guardian.
- Check for contraindications or precautions
 - See later in this chapter and the NIAC Immunisation guidelines for COVID-19 available at https://rcpi.access.preservica.com/uncategorized/IO_15ead882-dd37-4d61-a213-b692c930564c/
- Vaccinators who are vaccinating using a medicines protocol should check vaccine recipient's eligibility under the protocol
- Check the interval when administering a second or third dose
- Explain the procedure
- Answer questions
- Maintain privacy and dignity

15.5 Consumables needed

Low dead-volume syringes and/or needles are recommended. The low dead-volume syringe and needle combination should have a dead volume of no more than 35 microlitres.

- For dilution- 3ml syringes should be used and needle (length and size) 25 mm ,23-25 gauge (21 gauge or narrower needle)
- For administration- 1ml syringes should be used and needle (length and size) 25 mm ,23-25 gauge

Ampoules of Sodium Chloride 0.9% Solution for Injection will also be required. You will need 2.2ml of Sodium Chloride (0.9%) to dilute every vial

15.6 Infection prevention and control

- Prior to preparation and administration of COVID-19 vaccines, hand hygiene should be performed as per the "WHO five moments of hand hygiene" with emphasis on:
 - Before vaccine preparation
 - Before drawing up and administering the vaccine
 - Before and after each recipient contact
- PPE should be worn if necessary as per the current HPSC guidance for healthcare staff.
- It is not necessary to use a skin disinfectant prior to injection. If the skin at the injection site is visibly dirty, clean with soap and water. If an alcohol swab is used, delay injection for ≥30 seconds, to ensure the alcohol has evaporated.
- Gloves are not routinely recommended for vaccine preparation and administration
- There is no need to routinely check temperature either at registration or before vaccination.
- Follow HPSC standard precautions (sharps management, healthcare waste management etc.)
National Clinical Guideline No. 30 (2023) – Infection Prevention and Control (IPC)
<https://www.gov.ie/en/publication/a057e-infection-prevention-and-control-ipc/>.
- Check HPSC website for latest guidance on infection prevention and control for healthcare workers:
- National Clinical Guideline No. 30 (2023) – Infection Prevention and Control (IPC)
<https://www.gov.ie/en/publication/a057e-infection-prevention-and-control-ipc/>.

Vaccine Dilution and Preparation for Administration

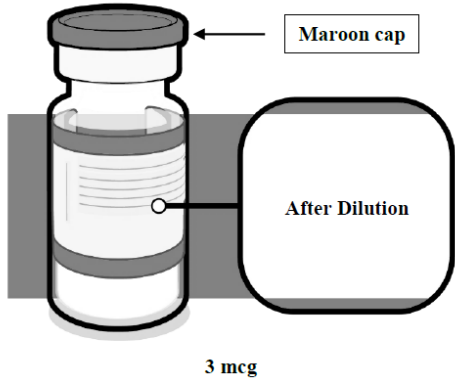
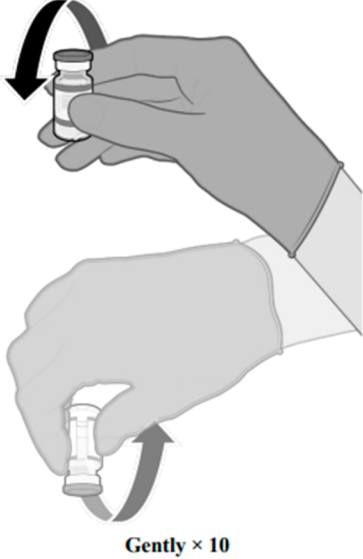
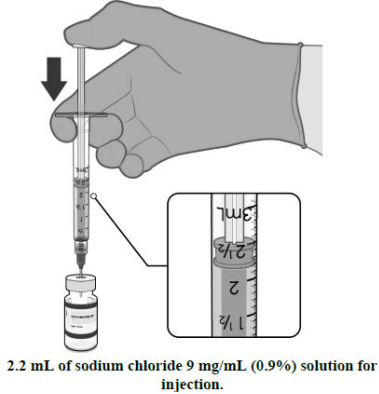
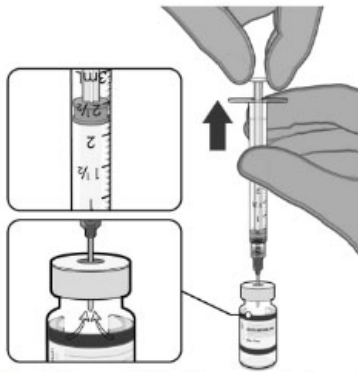
 <p>Figure 1: Image of the vial</p>	<p>Prior to dilution</p> <ul style="list-style-type: none"> • Perform hand hygiene • Check that you are using the correct formulation <ul style="list-style-type: none"> ◦ Verify that the vial of Comirnaty® COVID-19 mRNA vaccine (Comirnaty® MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION (INFANTS AND CHILDREN 6 MONTHS TO 4 YEARS))
 <p>Figure 2: Mixing Prior to Dilution</p>	<p>Preparation for dilution</p> <p>Prepare the equipment needed for dilution:</p> <ul style="list-style-type: none"> • A clean tray • One Comirnaty® COVID-19 mRNA vaccine multidose vial • One plastic ampoule of sodium chloride 0.9% solution for injection <ul style="list-style-type: none"> ◦ This should not be kept in the fridge • A needle and a syringe to dilute (using a 21 gauge or narrower needle) • Two 70% alcohol swabs <p>Check the use before date and time on the box containing the vials.</p> <p>Before dilution mix by inverting vaccine vial gently 10 times, do not shake. Inspect the liquid in the vial prior to dilution, the liquid is a white to off-white suspension and may contain opaque amorphous particles. Do not use if the liquid is discoloured or if other particles are observed.</p>
 <p>2.2 mL of sodium chloride 9 mg/mL (0.9%) solution for injection.</p>	<p>Dilution</p> <p>Dilution is undertaken using aseptic techniques</p> <ul style="list-style-type: none"> • Take one ampoule of sodium chloride and check expiry date • Clean with 70% alcohol swab • Open the ampoule by twisting the cap • Connect the syringe tightly (No needle is required) • Follow aseptic technique <ul style="list-style-type: none"> ◦ Do not touch the key parts of the ampoule and syringe • Withdraw 2.2ml of sodium chloride 0.9% solution for injection

Figure 3: Dilution with 2.2 mL of sodium

chloride
9 mg/mL
(0.9%)



Pull back plunger to 2.2 mL to remove air from vial.

Figure 4: Pull back plunger to 2.2 mL to remove air from vial

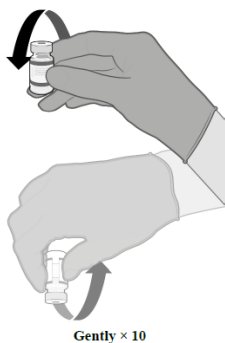
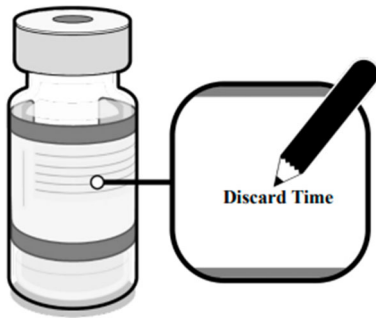


Figure 5: Invert the diluted solution

- NB: The volume of diluent is different than for other age groups
- Cross check with a colleague
- Attach the needle to the syringe
- Insert diluent into the vaccine vial (Figure 3)
- You may feel some pressure in the vial as you add the diluent
- Do not remove the needle and syringe from the vial until you have equalised the vial pressure by slowly withdrawing 2.2ml of air into the empty diluent syringe before removing the needle from the vial (Figure 4)
- Gently invert the diluted solution 10 times. Do not shake.
- Inspect the vial
- The diluted vaccine should be an off-white suspension
- Do not use if vaccine is discoloured or contains particulate matter

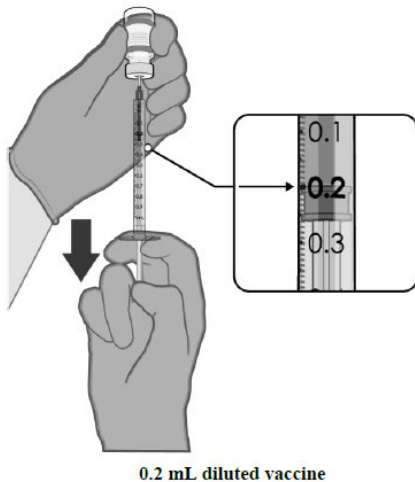


Record appropriate date and time.
Use within 12 hours after dilution.

Figure 6: Label the diluted vial with the discard time and date

Labelling the diluted vial

- Label the diluted vial with the discard time and date (12 hours after time of dilution) using a 24-hour format. Do not use it after this date
 - E.g. time of dilution was 08:00 20/12/2022. The discard time and date is 20:00 20/12/2022.
- After dilution, the vial contains up to 12 doses of 0.2ml.
 - The volume of each dose is smaller than the adult dose. Be alert that this volume is the same volume as that given to 5 to 11 year olds, but the dose is different (3 micrograms per dose for 6 months to 4 year old and 10 micrograms per dose for 5 to 11 year olds).
- Diluted vaccines can be stored between +2°C to +30°C but must be used within 12 hours following dilution.
- Bring the vial to your vaccination table/site.



0.2 mL diluted vaccine

Figure 7: Withdraw 0.2ml of diluted product

Vaccine Dose Preparation

- Check that the time of vaccine dilution was within the last 12 hours.
- Perform hand hygiene
- Clean top of vial with a single use 70% alcohol swab and allow it to air dry fully
- Attach 25mm, 23-25 gauge needle to 1ml syringe
- Withdraw 0.2ml of diluted product.
- Make sure the correct dose is drawn up as a smaller dose may not provide protection
- Before the needle is withdrawn, ensure all air bubbles have been removed
- Do not change the needle between the vial and patient unless the needle is contaminated or damaged.

15.7 Vaccine Administration

- Administer the vaccine to the patient intramuscularly (via IM injection)
 - For infants aged 6 months to 11 months, the recommended injection site is the anterolateral aspect of the thigh.
 - For children aged 1 year to 3 years of age, either the anterolateral aspect of the thigh or the deltoid muscle can be used as the injection site.
 - For children aged 3 years and older, the recommended injection site is the deltoid muscle.

Recipient's Age	Site	Needle length & Size
6months to <12 months	Vastus lateralis muscle	25 mm 23-25 gauge
1 to 4 years	Vastus lateralis or deltoid muscle (depending on muscle mass)	25 mm 23-25 gauge

- Dispose the syringe and the needle into the sharps bin
- If more than ten 0.2ml doses can be safely and accurately withdrawn from a diluted vial, they can be used as valid doses.
- There is a maximum of 12 doses in each vial
- Do not leave the empty vials unattended
- Dispose of the empty vials safely into a sharps bin
- Low dead space syringes and needles should be used if available in order to maximise the number of doses that can be drawn from the vial
- There should be no pooling of vaccine solution from different vials

Method of IM Vaccine Administration

- Intramuscular injection technique is to be used
 - For infants aged 6 months to 11 months, the recommended injection site is the vastus lateralis muscle (anterolateral aspect of the thigh).
 - For children aged 1 year to 3 years of age, either the deltoid muscle or the vastus lateralis muscle (anterolateral aspect of the thigh) can be used as the injection site.
 - For children aged 3 years and older, the recommended injection site is the deltoid muscle.

IM injection into the deltoid muscle

- The light triangle in the below figure indicates the site for IM injection into the deltoid muscle. The upper border of the triangle is approximately two finger-breadths / 2.5cms below the acromion process and the apex is at the midpoint of the humerus.



Figure 8: IM injection site into the deltoid muscle

IM injection site is the Vastus lateralis muscle

- The vastus lateralis muscle is located on the anterolateral aspect of the thigh, from one of the patient's hand breadths below the greater trochanter to one hand's breath above the knee. The middle third of the muscle is the site for injections. The width of the injection site extends from the mid-line of the thigh anteriorly to the mid-line of the outer thigh.
- The injection site is the middle third of the Vastus lateralis, in the anterolateral thigh (shaded area)

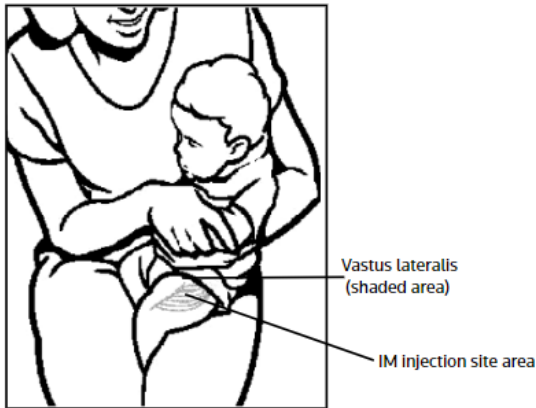


Figure 9: IM injection site into the middle third of the vastus lateralis

At the injection site (whether using deltoid or vastus lateralis), spread the skin taut between the thumb and forefinger with the non-dominant hand. Do not bunch up the skin as this leads to administering the vaccine into subcutaneous tissue inadvertently.

- Further information is available at https://rcpi.access.preservica.com/uncategorized/IO_67b1011b-87ed-4b8a-94ac-416bfe112caa/

Positioning for vaccination

For infants:

- Sit the infant on parent/guardian's lap, facing to the side.
- One arm is tucked under the parent/guardian's armpit (cuddle position). The infant's other arm is held in the parent/guardian's arms.
- Both of the infant's legs are anchored between the parent/guardian's thighs

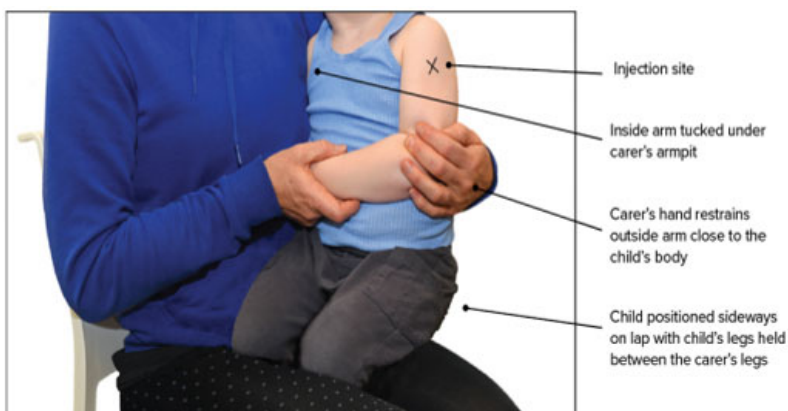


Figure 10: Positioning of infants (Source: Australian Immunisation handbook)

For older children:

- The child sits on the parent/guardian's lap or stands in front of them while the parent/guardian is sitting
- The parent/guardian embraces the child during the process, holding both the child's arms as they do so both of the child's legs are anchored between the parent/guardian's thighs
- Some children may prefer to sit on the guardian/parent's lap or sit independently
- Alternatively, the positioning for infants may also be used



Figure 11: Positioning for older children (Source: *Immunisation Guidelines of the National Immunisation Advisory Committee*)

Techniques for vaccinating children

- Be honest and calm. Take time to explain in simple terms what to expect. Explain that the child may feel a little pinch and it will go away very quickly.
- Use words like “pressure” or “pinch” rather than “pain” or “shot”
- Distraction techniques can help in reducing pain and anxiety during vaccination. If possible, keep the distraction going after the vaccine is given.
 - Looking at toys, books, etc.
 - Pointing out interesting things in the room
 - Telling or reading stories
 - Taking deep breaths to help “blow out” the pain
 - Counting from 5 backwards

What to do if the child does not want to be vaccinated

- Only one person should hold the child for vaccination at any time (to minimise risk of needle stick injury)
- If the child cannot be held/positioned by the parent/carers so that vaccination is possible, then the child should not be vaccinated
- Repeated attempts to vaccinate the child are unlikely to help
- Check with your clinical lead for advice
- It may be better to bring the child back another time with a parent/guardian if they were not present
- They may benefit from vaccination during quiet times

Prevention and Management of Syncope in Vaccination Clinics

- Syncope is rare in babies and young children; it is more common in adolescents
- Syncope episodes mostly occur within 15 minutes of vaccine administration
- Reassurance about the procedure may help to prevent fainting
- Recipients should be seated (or lying down, if past history of fainting) when being administered their vaccines in case of an immediate faint
- There should be facilities in place in case of fainting
 - So that the patient can be placed in a recumbent position/lie down or sit with head between knees for several minutes if lying down is not possible
- It may be helpful to loosen any tight clothing and apply cool, damp cloths to the person's face and neck
- Further information is available at www.immunisation.ie and at <https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/>

15.8 Contraindications and precautions to COVID-19 vaccination in children aged 6 months to 4 years

Contraindications

- Anaphylaxis following a previous dose of the vaccine or any of its constituents (including polyethylene glycol (PEG) and trometamol).

Appropriate support should be available in case of anaphylaxis or fainting after vaccine administration.

Precautions should be in place to minimise injury from fainting.

Precautions

- Acute severe illness; defer until recovery.
- Previous history of myocarditis or pericarditis after any COVID-19 vaccine - seek specialist advice.
- Vaccination should be postponed in children with a previous history of MIS-C, until clinical recovery or until 90 days or more since diagnosis, whichever is the longer.

The following are not contraindications or precautions to vaccination:

- Food allergy (non-anaphylactic)
- Family history of allergy, including anaphylaxis
- Previous local reaction to any vaccine
- Underlying asthma
- Hay fever
- Hereditary angioedema
- Contact dermatitis to PEG containing cosmetic product
- NSAID allergy
- Chronic spontaneous urticaria

15.9 Post-vaccination Procedures

Documentation post-vaccination

- Record vaccine batch number in the record/IT system
 - It will automatically link to the expiry date, so there is no need to record the expiry date
- Boxes delivered by NCCS will be labelled with a "use before" date and time
- This "use before" date and time should be recorded in the patient record
- Give the record card to the parent/guardian

Observation post-vaccination

- Vaccine recipients: 15 minutes of observation
- Those with a history of mastocytosis: 30 minutes of observation

- Those with immediate itching, swelling or urticarial reaction at the vaccination site: 30 minutes or longer as clinically indicated

Advice following vaccination

- Parent/guardian should be advised that COVID-19 vaccines may cause a fever which usually resolves within 48 hours. This is a common, expected reaction and isolation and further investigation is not required unless COVID-19 is suspected.
- If fever lasts for >48 hours, or if other symptoms of COVID-19 are present, the person should self-isolate and seek medical advice
- Paracetamol or ibuprofen can be taken after vaccination if the child develops pain, fever, or myalgia
- Advise the child's parent/guardian that vaccinated children may still get infected and transmit the virus so they should continue to follow all current public health guidance to protect themselves and others
- Please refer to the NIAC immunisation guidelines available at https://rcpi.access.preservica.com/uncategorized/IO_15ead882-dd37-4d61-a213-b692c930564c/

15.10 Adverse Events

In clinical trials for children in this age group, no new safety concerns were observed. However, the study size did not allow for detection of rare or very rare adverse events or to evaluate whether the characteristics of identified but rarer risks, such as myocarditis, differ compared with the older populations.

In the US, over one million children aged 6 months-5 years have received at least one dose of either Comirnaty® or Spikevax. The CDC reviewed adverse events and the most commonly reported symptoms were irritability or crying, sleepiness, loss of appetite and fever. Almost all (98%) reports were for non-serious events. Of the serious events reported, two were likely attributable to the vaccination, one febrile convulsion and one anaphylaxis associated with a dosing error. No cases of myocarditis were reported.

The most frequent adverse reactions in those that received any primary course dose included:

- in infants 6-23 months of age, irritability (> 60%), drowsiness (> 40%), decreased appetite (>30%), tenderness at the injection site (> 20%), injection site redness and fever (> 10%)
- in children 2-4 years of age, pain at injection site and fatigue (> 40%), injection site redness and fever (> 10%).

A higher rate of pyrexia was seen after administration of the second dose.

Reporting of adverse events following immunisation

This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions to the HPRA.

<https://www.hpra.ie/homepage/about-us/report-an-issue/human-adverse-reaction-form>

15.11 Clinical Considerations

Vaccination after COVID-19 infection

Unvaccinated

Those who are unvaccinated and develop SARS-CoV-2 infection should complete a primary vaccination course, with the first dose at least four weeks after diagnosis or onset of symptoms, or four weeks from the first PCR positive specimen in those who are asymptomatic.

Those with persisting symptoms following COVID-19 may be vaccinated, unless there is evidence of recent clinical deterioration.

Partially vaccinated

Those who have had SARS-CoV-2 infection after their first dose of COVID-19 vaccine should be given the subsequent dose at least four weeks after diagnosis or onset of symptoms.

In those who have SARS-CoV-2 infection more than seven days after the second vaccine dose, a third dose of the primary series is not required.

For those with infection within seven days of their second dose they should complete the primary series after an interval of 8 weeks.

Efficacy

In a study 1,254 children aged 6 months-4 years who were SARS-CoV-2 negative at baseline received three doses of either Comirnaty® (n=873) or placebo (n=381). The median follow-up period following dose three was 1.3 months. An estimated vaccine efficacy (VE) against SARS-CoV-2 infection of 73% was observed. A total of 21 cases of SARS-CoV-2 were reported in the placebo group and 13 cases in the vaccinated group.

Duration of immunity

There is insufficient information to determine the duration of protection from the vaccine. Vaccine recipients may not have optimal protection **until seven days after the third dose**, and the vaccine may not protect all vaccinees. Vaccinated children should continue to follow current public health guidance to protect themselves and others.

Co-administration with other vaccines

In this age group, there must be at least a 2 week interval between the administration of the COVID-19 vaccine and any other vaccines. No interaction studies in young children have been performed on co-administration of Comirnaty® with childhood vaccines. **Priority should be given to other routine immunisations.** Until there is more evidence it is prudent to separate COVID-19 vaccination in children aged 6 months-4 years from other vaccines for a period of 14 days.

As a precaution, if the child has recently received the monkeypox vaccine (Imvanex or Jynneos), they need to wait 4 weeks before they get their COVID-19 vaccine because of the unknown risk of myocarditis.

Children who are immunocompromised

Children who are immunocompromised due to disease or treatment may be vaccinated if they have no contraindications. There are currently no indications for additional doses or booster doses for this age group. The primary course of 3 doses of Comirnaty® 3 micrograms (0.2ml) is currently the only recommendation for COVID-19 vaccination for children aged 6 months to 4 years including those with immunocompromise. Children with planned immunosuppressing therapy should ideally complete vaccination two weeks before treatment. The recommended minimum interval may be used. Specialists should consider the child's risk and likelihood of disease exposure, and provide advice based on knowledge and understanding of their immune status and likely immune response to vaccination.

Vaccination of those with bleeding disorders or on anticoagulants

Individuals with a bleeding disorder or receiving anticoagulant therapy may develop haematomas in IM injection sites. Prior to vaccination, inform the parent/guardian about this risk.

For those with thrombocytopenia (platelet count $<50 \times 10^9/L$), consult the supervising consultant. For children with mild bleeding disorders or on maintenance dose Emicizumab (Hemlibra) do not require haemostatic cover for vaccination.

Those with inherited coagulopathies receiving factor replacement therapy should receive it on the day of vaccination, prior to IM vaccination. If there is uncertainty about the need for replacement therapy, contact the child's supervising consultant.

Those receiving long-term anticoagulation with either warfarin or heparin are not considered to be at higher risk of bleeding complications following immunisation. There is no reason to expect that there is a greater risk of bleeding complications with the newer types of anticoagulants and antiplatelet agents, than with other anticoagulants.

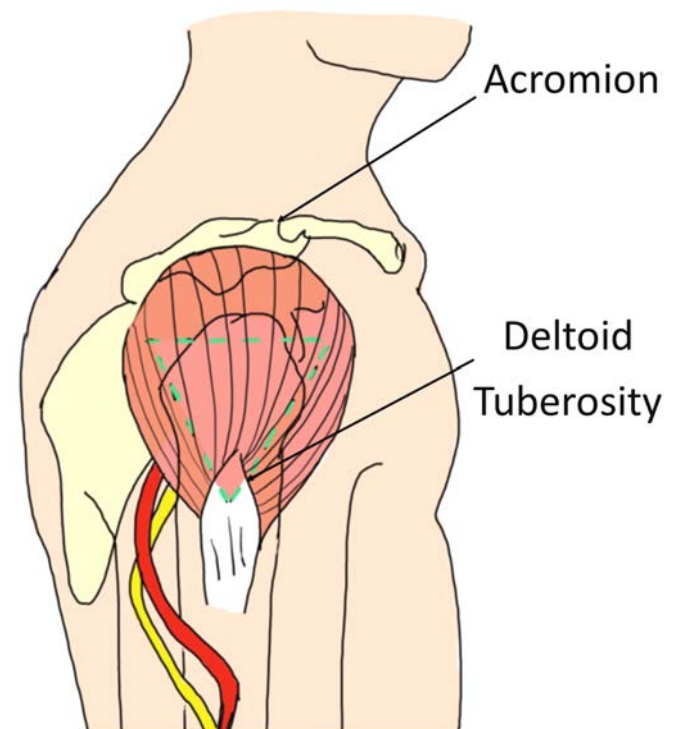
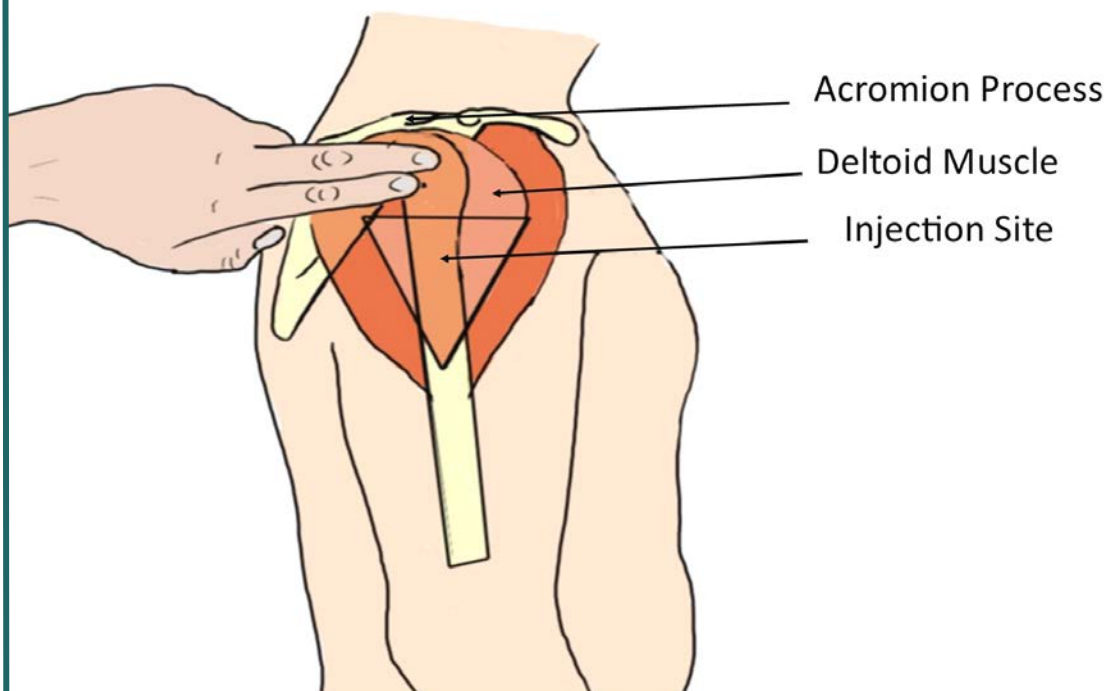
Technique for IM injections in persons with bleeding disorders or on anticoagulants:

- Only one injection per muscle mass should be given at each visit. Use a 23 or 25 gauge needle to reduce the pressure gradient and cause less trauma to the tissue. The vaccine should be injected slowly (≥ 5 seconds) to reduce the risk of tissue damage.
- Firm pressure should be applied to the site for 5 to 10 minutes after injection.
- Stabilisation of the limb will reduce the risk of a haematoma.
- The site should not be rubbed or massaged.
- Instruct the parent/guardian to monitor the injected limb and to report any concerns to their supervising consultant.

Useful links

- Frequently Asked Questions about COVID-19 vaccines for people with pre-existing allergic conditions <https://www.rcpi.ie/news/releases/frequently-asked-questions-about-covid-19-vaccines-for-people-with-pre-existing-allergic-conditions/>
- Immunisation Guidelines for Ireland: Chapter 5a COVID-19. <https://www.rcpi.ie/healthcare-leadership/niac/immunisation-guidelines-for-ireland>
- Information for women who are pregnant or breastfeeding and their doctors about COVID-19 vaccine <https://www.rcpi.ie/news/releases/information-for-women-who-are-pregnant-or-breastfeeding-about-the-covid-19-vaccine-update/>
- HSE Management of cold chain guidance (2-8°C) <https://www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/sopnio01.pdf>
- HSE Guidelines for maintaining the vaccine cold-chain in vaccine cool boxes <https://www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/sopnio02.pdf>
- Licensed documentation for vaccines: Summary of Product Characteristics (SmPC) for health care professionals, and Package Leaflet (PL) for the public, available via the European Medicines Agency websites <https://www.ema.europa.eu/en>.
- Health Products Regulatory Authority. Human Medicines Adverse Reaction Report <https://www.hpra.ie/homepage/about-us/report-an-issue/covid-19-vaccine-adverse-reaction>
- HPSC COVID-19 guidance www.hpsc.ie

APPENDIX A: INTRAMUSCULAR INJECTION TECHNIQUE

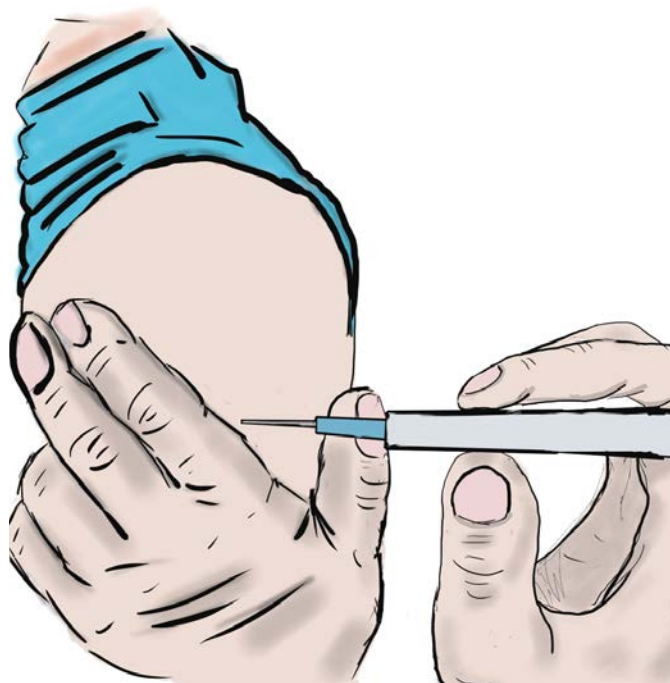


1 Landmark injection site

Base of triangle: Two finger widths down from the acromion process;
Bottom edge: At an imaginary line drawn from the axilla.

2 Identify injection site

The recommended site is the middle of the triangle.
Do not inject too high or too low.



3 Administer

At the injection site spread the skin taut between the thumb and forefinger with the non-dominant hand.
Do **NOT** bunch up the skin.
Inject at a 90-degree angle. Inject medication over 1-2 seconds.



Swift needle entry

Slow injection of medication

Swift needle withdrawal



Less pain

4 Technique

Swift needle entry, slow injection of medication, swift needle withdrawal
= less pain



APPENDIX B: SOP

Guidance for management of Comirnaty (Pfizer/BioNTech) COVID-19 Vaccine from time of delivery at sites up to the time of administration.

This document contains two sections:

Section 1 contains general information for all Comirnaty presentations

- 1. Background**
- 2. Responsibilities**
- 3. Scope**
- 4. Purpose**
- 5. Consumables, Patient Information Leaflet (PIL) & Record Cards and Other Equipment**
- 6. Health & Safety**

Section 2 contains 5 appendices with specific detail pertaining to each vaccine product.

- i. Appendix 1(a) – Appendix 1(b) refer to vaccine for 12 years and older,**
 - a. Comirnaty Original/Omicron BA.4-5 (15/15 micrograms)/dose dispersion for injection - Primary and Booster vaccine, RTU - Grey cap.**
 - b. Comirnaty Omicron XBB.1.5 30 micrograms/dose dispersion for injection– Booster vaccine, RTU – Grey cap**
- ii. Appendix 2(a) – Appendix 2 (b) refer to vaccine for 5-11 years**
 - a. Comirnaty Original/Omicron BA.4-5 (5/5 micrograms)/dose concentrate for dispersion for injection - Primary and Booster vaccine - Orange Cap**
 - b. Comirnaty Omicron XBB.1.5 10 micrograms/dose concentrate for dispersion for injection– Booster vaccine –Orange cap**
- iii. Appendix 3 refers to vaccine for children 6 months to 4 years.**
 - Comirnaty 3 micrograms/dose concentrate for dispersion for injection –Maroon cap**

This document is under regular review and updated when relevant new information becomes available. Please check www.immunisation.ie for the current version.

1. Background

Comirnaty COVID-19 Vaccines are delivered by HSE National Cold Chain Service (NCCS) at a temperature of +2 °C to +8 °C and therefore in a thawed state. The NCCS will update the expiry date and affix a “HSE SCAN ME” label detailing the new reduced shelf-life (= USE BEFORE date and time). Do not re-freeze.

Comirnaty formulations (GREY, ORANGE and MAROON caps) have a number of specifications in common. All products are multidose vials and contain Trometamol.

Additional information about the vaccination programme is available in the Clinical Guidance for COVID-19 Vaccination document available at www.immunisation.ie.

All SmPCs are available at:

<https://www.medicines.ie/medicines/list/all/page-1/per-page-25?query=comirnaty>

2. Responsibilities

The Responsible Person should ensure that Comirnaty COVID- 19 vaccines are managed, as outlined in this Guidance document.

3. Scope

The scope of this document is to provide a set of standardised procedures for the management of Comirnaty COVID- 19 vaccines at all vaccination sites

4. Purpose

The purpose of this document is to outline the management of Comirnaty vaccines and to provide supporting guidance in relation to:

- Receipt of vaccine
- Vaccine decommissioning
- Shelf-Life
- Storage & Transportation
- Presentation and preparation
- Consumables, Patient Information Leaflet (PIL) & Record Cards and Other Equipment
- Stock Control, Security & Monitoring of Wastage
- Health & Safety

The documents provided may be used as templates to be adapted for local use or may be used as reference sources to check that existing local procedures are robust and comprehensive.

4.1 Receipt of vaccines

- Upon arrival at your site record the maximum, minimum and current temperature of the fridge/s, and reset after recording.
- Prior to receipt of vaccine delivery, ensure the temperature is between +2 °C and +8 °C.
- Sign for receipt of the vaccines. Vaccines will be at a temperature of +2°C to +8°C when delivered by NCCS.
- Check against the delivery docket (note: the expiry date on the docket may differ to printed expiry on carton and vial- the delivery docket carries the updated and correct expiry date)
- Scan or record the details of the HSE SCAN ME label and immediately place the vaccines (retained in original boxes to protect vials from light) in the fridge.

For additional information please see the following document

<https://www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/sopnio01.pdf>

4.2 Vaccine Decommissioning

All boxes have been re-labelled and decommissioned by NCCS.

Comirnaty BA.4-5 formulations:

In consequence of the extension of the shelf-life, affected batches will appear as expired. The labelled expiration date on the product and the stored data in the NMVS repository is not taking the extended shelf-life into account. Please refer to “Dear Healthcare Professional” letter enclosed in the delivery box.

4.3 Shelf-Life

4.3.1 Expiry date:

For Comirnaty BA.4-5 formulations and Comirnaty 3 micrograms/dose shelf life has been extended to 24 months while stored in ULT freezers (-90°C to -60°C) and as a consequence the printed expiry date on the box and vial label may have been exceeded when these vials are delivered.

Note: The relevant expiry date will be printed on the delivery docket. The delivery box will also include a letter explaining this. This process is managed by NCCS and no action is required by the vaccinator.

For Comirnaty XBB.1.5 formulations the shelf life is 18 months when stored in ULT freezers (-90°C to -60°C).

4.3.2 USE BEFORE date and time

The USE BEFORE date and time reflects the duration the unopened vial can be stored at +2°C to +8°C, which is up to **10 weeks**. The USE BEFORE date and time must remain within the shelf-life and replaces the expiry date. All boxes containing Comirnaty will be labelled by NCCS with USE BEFORE date and time label.

The USE BEFORE date and time specified on the label indicates the time by which the vial must be used irrespective of the expiry date on box or vial.

Record the USE BEFORE date in the patient's record and on COVAX.

4.3.3 DISCARD date and time

Discard date and time must be written on the vial once the vial is initially punctured. This is calculated by adding **12 hours** to the time of first puncture. The vaccine can be stored at temperature between +2 °C and +30°C during this period.

From a microbiological point of view, unless the method of opening precludes the risks of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.

The Discard time cannot exceed the USE BEFORE date and time. If the time remaining between first puncture and USE BEFORE date and time is less than the allowed discard time of 12 hours then the discard time must reflect the USE BEFORE date and time. All doses must be administered before the USE BEFORE date and time or else doses must be discarded.

4.4 Storage & Transportation

During storage, minimise exposure to room light, and avoid exposure to direct sunlight and ultraviolet light. Vials can be handled in room light conditions.

An appropriate container should be used for transportation to minimize the potential for vials to be jostled. If vials are inadvertently bumped, they should be righted, however the risk to the product is minimal and vials, which are temporarily knocked over, may still be used.

Unopened vials can be stored and transported for 10 weeks at +2 °C to +8 °C (within USE BEFORE date and time). Unopened vials can be stored for 12 hours prior to first puncture at room temperature (+8 °C to +30 °C)

Vials can be stored for 12 hours after first puncture or dilution, at temperature (+2 °C to +30 °C) which includes up

to 6 hours transportation time.

The following information is intended to guide healthcare professionals only in case of temporary temperature excursion:

Stability data indicate that the unopened vial is stable for up to 10 weeks when stored at temperatures from -2 °C to 2 °C, within the 10-week storage period between +2 °C and +8 °C and up to 24 hours at temperatures of +8 °C to +30 °C, including up to 12 hours following first puncture.

4.5 Presentation and Preparation

- All formulations are packed in original boxes of 10 vials.
- Grey cap Vials (vaccines for 12 years and older) contain 6 doses
- Orange and Maroon cap Vials (vaccines for infants and children) contain 10 doses

Vial verification is essential.

- Comirnaty Original/Omicron BA.4-5 (15/15 micrograms)/dose dispersion for injection - Grey cap.
- Comirnaty Omicron XBB.1.5 30 micrograms/dose dispersion for injection – Grey cap
- Comirnaty Original/Omicron BA.4-5 (5/5 micrograms)/dose concentrate for dispersion for injection - Orange Cap.
- Comirnaty Omicron XBB.1.5 10 micrograms/dose concentrate for dispersion for injection – Orange cap
- Comirnaty 3 micrograms/dose concentrate for dispersion for injection- Maroon cap.

Preparation: **c.f. Individual Presentation Appendices 1 to 3**

Where diluent is required, only Sodium chloride (0.9%) for injection is to be used. Bacteriostatic saline or other diluents must **NOT** be used.

Do not pool excess vaccine from multiple vials.

The vaccine should not be mixed in the same syringe with any other vaccines or medicinal products.

The preferred site is the deltoid muscle of the upper arm (except in Infants).

Do not inject the vaccine intravascularly, subcutaneously or intradermally.

5. Consumables, Patient Information Leaflet (PIL) & Record Cards and Other Equipment

A national distribution service will provide all necessary supplies, to handle, prepare and administer the vaccine including PPE and critical clinical and non-clinical consumables. These are not included in this SOP.

Other Equipment includes:

Anaphylaxis Kits :Refer to National Immunisation Advisory Committee Guidelines

<https://www.hse.ie/eng/health/immunisation/hcpinfo/schoolproghcp/protocols/anaphylaxis2016.pdf> The epinephrine will be provided by a pre-determined community/ hospital pharmacy as agreed by the lead governance organization CHO/HG.

Storage Equipment: A pharmaceutical fridge must be used to store vaccines. The fridge should be set to maintain the temperature at +5 °C +/- 3 °C, and alarms should take into account the need to maintain the temperature above +2 °C and less than +8 °C.

Fridges should be validated and monitored in accordance with existing local procedures.

6. Stock Control, Security & Monitoring of Wastage

A physical stock count of COVID-19 vaccine vials should be completed and it should match the stock count recorded on the IT system.

Sites will need to ensure that vaccines are stored securely at all points between receipt and use or disposal. All waste must be handled in such a way as to prevent theft and /or misuse, both on site and after removal from the site.

Unopened vials (in original cartons) must be returned to NCCS for destruction following the routine protocol for all expired /damaged vaccines.

Dispose empty or partial empty vials into sharps bins safely as per health care management policy. Dispose syringes and needles into sharps bins according to normal local waste management procedures.

Original cartons must have their labels defaced using permanent black marker pens, and placed into appropriate waste sack for incineration, as soon as possible after they become empty.



7. Health & Safety

There are no special handling requirements for routine handling and dealing with spillages of Comirnaty COVID-19 vaccine.

Health and Safety risk assessments should be undertaken locally to ensure these risks are adequately controlled.

COMIRNATY COVID-19 mRNA Vaccine (nucleoside modified) Formulations Guide for different age groups

12 Years and older

Formulation and Name of the Medicinal Product	12 years and older, Ready to use, Omicron XBB.1.5 30 micrograms/dose dispersion for injection	12 years and older, Ready to use, Original/Omicron BA.4-5 (15/15 micrograms)/dose dispersion for injection
Vial Cap Colour	Grey Omicron XBB.1.5 	Grey Original/Omicron BA.4-5 
Dosage	30 mcg of raxtozinameran	15 mcg of tozinameran and 15 mcg of famtozinameran
Injection Volume per Dose	0.3 mL	0.3 mL
Dilution	NO DILUTION	NO DILUTION
Amount of Diluent Needed per Vial*	NO DILUTION	NO DILUTION
Doses per Vial	Multi-dose vial contains 6 doses	Multi-dose vial contains 6 doses
Fill Volume per Vial	2.25 mL for multi-dose vial	2.25 mL for multi-dose vial
ULT Freezer (-90 °C to -60 °C)	18 months (shelf life)	2 years (shelf life) [†]
Freezer Storage Time (-25 °C to -15 °C)	DO NOT STORE	DO NOT STORE
Refrigeration Storage Time (2 °C to 8 °C)	10 weeks	10 weeks
Room Temperature (8 °C to 30 °C)	12 hours prior to first puncture (including any thaw time)	12 hours prior to first puncture (including any thaw time)
After First Puncture (2 °C to 30 °C)	Discard after 12 hours	Discard after 12 hours

5 – 11 Years

Formulation and Name of the Medicinal Product	5 to 11 years old, Dilute to use, omicron XBB.1.5 10 micrograms/dose concentrate for dispersion for injection	5 to 11 years old, Dilute to use, Original/Omicron BA.4-5 (5/5 micrograms)/dose concentrate for dispersion for injection
Vial Cap Colour	Orange Omicron XBB.1.5 	Orange Original/Omicron BA.4-5 
Dosage	10 mcg of raxtozinameran	5 mcg of tozinameran and 5 mcg of famtozinameran
Injection Volume per Dose	0.2 mL	0.2 mL
Dilution	Dilution required	Dilution required
Amount of Diluent Needed per Vial*	1.3 mL	1.3 mL
Doses per Vial	10 doses per vial (after dilution)	10 doses per vial (after dilution)
Fill Volume per Vial	1.3 mL	1.3 mL
ULT Freezer (-90 °C to -60 °C)	18 months (shelf life)	2 years (shelf life) [†]
Freezer Storage Time (-25 °C to -15 °C)	DO NOT STORE	DO NOT STORE
Refrigeration Storage Time (2 °C to 8 °C)	10 weeks	10 weeks
Room Temperature (8 °C to 30 °C)	12 hours prior to dilution (including any thaw time)	12 hours prior to dilution (including any thaw time)
After First Puncture (2 °C to 30 °C)	Discard after 12 hours	Discard after 12 hours

6 Months – 4 Years

Formulation and Name of the Medicinal Product	6 months to 4 years old, Dilute to use 3 micrograms/dose concentrate for dispersion for injection
Vial Cap Colour	Maroon 
Dosage	3 mcg
Injection Volume per Dose	0.2 mL
Dilution	Dilution required
Amount of Diluent Needed per Vial*	2.2 mL
Doses per Vial	10 doses per vial (after dilution)
Fill Volume per Vial	0.4 mL
ULT Freezer (-90 °C to -60 °C)	2 years (shelf life) [†]
Freezer Storage Time (-25 °C to -15 °C)	DO NOT STORE
Refrigeration Storage Time (2 °C to 8 °C)	10 weeks
Room Temperature (8 °C to 30 °C)	12 hours prior to dilution (including any thaw time)
After First Puncture (2 °C to 30 °C)	Discard after 12 hours

Appendix 1 (a) and 1 (b)

These two appendices have all handling and preparation details in common, which will follow the description of Appendix 1(a) & Appendix 1(b)

Appendix 1(a) and Appendix 1(b) refer to Comirnaty vaccines for 12 years and older

Appendix 1 (a)

Comirnaty Original/Omicron BA.4-5 (15/15 micrograms)/dose dispersion for injection –RTU - Grey cap. (12 years and Older)

- a. Comirnaty Original/Omicron BA.4-5 (15/15 micrograms)/dose dispersion for injection is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2, **in individuals 12 years of age and older for primary and booster doses against COVID-19**
- b. One dose (**0.3 ml**) contains 15 micrograms of tozinameran and 15 micrograms of famtozinameran, a COVID-19 mRNA Vaccine (embedded in lipid nanoparticles).
- c. Verify that the vial has a grey plastic cap and the product name is Comirnaty Original/Omicron BA.4-5 (15/15 micrograms)/dose dispersion for injection.

Appendix 1 (b)

Comirnaty Omicron XBB.1.5 30 micrograms/dose dispersion for injection, RTU – Grey cap. (12 years and older)

- a. Comirnaty Omicron XBB.1.5 30 micrograms/dose dispersion for injection is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2, **in individuals 12 years of age and older for booster doses against COVID-19**
- b. One dose (0.3 mL) contains 30 micrograms of raxtozinameran, a COVID-19 mRNA Vaccine (embedded in lipid nanoparticles).
- c. Verify that the vial has a grey plastic cap and the product name is Comirnaty Omicron XBB.1.5 30 micrograms/dose dispersion for injection

The following is applicable to all vials with GREY Caps:

- Ready to use- DO NOT DILUTE
- The vaccine does not contain preservative and is provided as a multiple dose vial
- Excipients include Trometamol and Trometamol hydrochloride.
- Each vial contains 6 doses
- Each dose is 0.3ml
- Do not pool excess vaccine from multiple vials

Preparation:

- a. Gently mix by inverting vials 10 times prior to use. Do not shake.
- b. Prior to mixing, the thawed dispersion may contain white to off-white opaque amorphous particles.
- c. After mixing, the vaccine should present as a white to off-white dispersion with no particulates visible.
- d. Do not use the vaccine if particulates or discolouration are present
- e. **DO NOT DILUTE** prior to use.
- f. One vial contains 6 doses of **0.3 ml** (low dead-volume syringes and/or needles should be used)

- g. Each dose must contain **0.3 ml** of vaccine, if the amount of vaccine remaining in the vial after 6 doses withdrawn, can provide a full dose of **0.3 ml**, this is a valid dose
- h. Discard the vial and any excess volume in sharps bin
- i. May be stored at room temperature (+8 °C to +30 °C) for a total of 12 hours prior to the first puncture.
- j. After first puncture, the vial should be held between +2 °C to +30 °C.
- k. Record the appropriate Discard date/time on the vial.
- l. Vials should be discarded 12 hours after the first puncture.
- m. During storage, minimise exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.
- n. Do not refreeze thawed vials.

Appendix 2(a) and Appendix 2(b) refer to Comirnaty vaccines for 5-11 years

Appendix 2(a)

Comirnaty Original/Omicron BA.4-5 (5/5 micrograms)/dose concentrate for dispersion for injection- Orange Cap (5-11 years) - Dilute to use

- a. Comirnaty Original/Omicron BA.4-5 (5/5 micrograms)/dose concentrate for dispersion for injection is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2, in children aged 5 to 11 years **for primary and booster doses against COVID-19**
- b. One dose (0.2 ml) contains 5 micrograms of tozinameran and 5 micrograms of famtozinameran, a COVID-19 mRNA Vaccine (embedded in lipid nanoparticles).
- c. Verify that the vial has an orange plastic cap and the product name is **Comirnaty Original/Omicron BA.4-5 (5/5 micrograms)/dose concentrate for dispersion for injection**.

Appendix 2(b)

Comirnaty Omicron XBB.1.5 10 micrograms/dose concentrate for dispersion for injection - Orange Cap (5-11 years) - Dilute to use

- a. Comirnaty Omicron XBB.1.5 10 micrograms/dose concentrate for dispersion for injection is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2, in children aged 5 to 11 years **for booster doses against COVID-19**
- b. One dose (0.2 ml) contains 10 micrograms of raxtozinameran, a COVID-19 mRNA Vaccine (embedded in lipid nanoparticles).
- c. Verify that the vial has an orange plastic cap and the product name is **Comirnaty Omicron XBB.1.5 10 micrograms/dose concentrate for dispersion for injection**

The following is applicable to all vials with Orange Caps:

- The vaccine does not contain preservative and is provided as a multiple dose vial
- Excipients include Trometamol and Trometamol hydrochloride.
- Each vial contains 10 doses
- Each dose is 0.2ml
- Do not pool excess vaccine from multiple vials.

Preparation:

• **Verify that the vial has an orange plastic cap.**

- a. Allow the vial to come to room temperature and gently invert it 10 times prior to dilution. Do not shake.
- b. Prior to dilution, the dispersion may contain white to off-white opaque amorphous particles.
- c. The vaccine must be diluted in its original vial with 1.3 ml sodium chloride 9 mg/ml (0.9%) solution for injection, using a 21 gauge or narrower needle and aseptic techniques.
- d. After dilution with 1.3 ml of sodium chloride 9 mg/mL (0.9%) solution for injection the vial contains (2.6ml) 10 doses of 0.2 ml (10 mcg). Do not add more than 1.3 ml of diluent

IMPORTANT: regardless of the volume of the diluent vial, it must be used for ONE TIME dilution (after withdrawal, the remaining diluent must be discarded)

- e. Equalise vial pressure before removing the needle from the vial stopper by withdrawing 1.3 ml air into the empty diluent syringe.
- f. Gently invert the diluted dispersion 10 times. Do not shake.
- g. The diluted vaccine should present as a white to off-white dispersion with no particulates visible. Do not use the diluted vaccine if particulates or discolouration are present.
- h. After dilution, the vial contains 2.6 ml from which 10 doses of 0.2 ml can be extracted. Each dose must contain **0.2 ml** of vaccine, if the amount of vaccine remaining in the vial after 10 doses withdrawn, can provide a full dose of **0.2 ml**, this is a valid dose
- i. The diluted vials should be marked with the appropriate Discard date and time.
- j. After dilution, store at 2 °C to 30 °C and use within 12 hours. Discard any unused vaccine within 12 hours after dilution.
- k. Do not freeze or shake the diluted dispersion.

Appendix 3

Comirnaty 3 micrograms/dose concentrate for dispersion for injection –Maroon cap- (Infants and Children aged 6 months- 4 years)

- a. Comirnaty 3 micrograms/dose concentrate for dispersion for injection is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2, in infants and children aged 6 months to 4 years.
- b. One vial (0.4 mL) contains 10 doses of 0.2 mL after dilution, with 2.2ml of NaCl 0.9% solution for injection. One dose (0.2 mL) contains 3 micrograms of tozinameran, a COVID-19 mRNA Vaccine (embedded in lipid nanoparticles).
- c. Comirnaty 3 micrograms/dose is administered intramuscularly after dilution as a primary course of 3 doses (0.2 mL each). In infants from 6 to less than 12 months of age, the recommended injection site is the anterolateral aspect of the thigh. In individuals 1 year of age and older, the recommended injection site is the anterolateral aspect of the thigh or the deltoid muscle. As per NIAC guidelines, the dose of Comirnaty depends on the age at the time of the vaccination e.g. a four year old child who received the first dose of Comirnaty 3 micrograms and who is five years of age at the time of their second or third dose, should receive the next dose(s) of Comirnaty 10 micrograms.

The following is applicable to Comirnaty 3 micrograms - **Maroon Caps**:

- The vaccine does not contain preservative and is provided as a multiple dose vial
- Excipients include Trometamol and Trometamol hydrochloride.
- Each vial contains 10 doses
- Each dose is 0.2ml

- Do not pool excess vaccine from multiple vials.

Verify that the vial has a **maroon plastic cap**.

- Allow the vial to come to room temperature and gently invert it 10 times prior to dilution. Do not shake.
- Prior to dilution, the dispersion may contain white to off-white opaque amorphous particles.
- The vaccine must be diluted in its original vial with 2.2 ml sodium chloride 9 mg/ml (0.9%) solution for injection, using a 21 gauge or narrower needle and aseptic techniques.
- After dilution with 2.2 ml of sodium chloride 9 mg/mL (0.9%) solution for injection the vial contains (2.6ml) 10 doses of 0.2 ml (3 mcg) Do not add more than 2.2 ml of diluent

IMPORTANT: regardless of the volume of the diluent vial, it must be used for ONE TIME dilution (after withdrawal, the remaining diluent must be discarded)

- Equalise vial pressure before removing the needle from the vial stopper by withdrawing 2.2 ml air into the empty diluent syringe.
- Gently invert the diluted dispersion 10 times. Do not shake.
- The diluted vaccine should present as a white to off-white dispersion with no particulates visible. Do not use the diluted vaccine if particulates or discolouration are present.
- After dilution, the vial contains 2.6 ml from which 10 doses of 0.2 ml can be extracted. Each dose must contain **0.2 ml** of vaccine, if the amount of vaccine remaining in the vial after 10 doses withdrawn, can provide a full dose of **0.2 ml**, this is a valid dose
- The diluted vials should be marked with the appropriate Discard date and time.
- After dilution, store at 2 °C to 30 °C and use within 12 hours. Discard any unused vaccine within 12 hours after dilution
- Do not freeze or shake the diluted dispersion.

Guidance for management of Nuvaxovid XBB.1.5 (Novavax) COVID-19 vaccine from the time of delivery at sites up to the time of administration.

1. Background

Nuvaxovid XBB.1.5 (Novavax) COVID-19 vaccines are delivered by the HSE National Cold Chain Service (NCCS) at a temperature of +2 °C to +8 °C.

The SmPC is available at:

https://www.ema.europa.eu/en/documents/product-information/nuvaxovid-epar-product-information_en.pdf

Additional information about the vaccination programme is available in the Clinical Guidance for COVID-19 Vaccination document available at www.immunisation.ie.

2. Responsibilities

The Responsible Person should ensure that Nuvaxovid XBB.1.5 Covid-19 vaccines are managed as outlined in this guidance document.

3. Scope

The scope of this document is to provide a set of standardised procedures for the management of Nuvaxovid XBB.1.5. Separate documents are available for other COVID-19 vaccines.

4. Purpose

The purpose of this document is to outline the management of Nuvaxovid XBB.1.5 at the vaccination clinic level, and to provide supporting guidance in relation to:

- Receipt of vaccine
- Vaccine decommissioning
- Shelf-Life
- Storage
- Presentation and preparation
- Consumables, Patient Information Leaflet (PIL) & Record Cards and Other Equipment
- Stock Control, Security & Monitoring of Wastage
- Health & Safety

The documents provided may be used as templates to be adapted for local use or may be used as reference sources to check that existing local procedures are robust and comprehensive.

4.1 Receipt of vaccines

- Prior to receipt of vaccine delivery, ensure the fridge temperature is between +2 °C and +8 °C.
- Sign for receipt of the vaccines. Vaccines will be at a temperature of +2°C to +8°C when delivered by the NCCS.
- Check against the delivery docket.
- Place the vaccines immediately in a pharmaceutical fridge.

For additional information please see the following document:

<https://www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/sopnio01.pdf>

4.2 Vaccine Decommissioning

Nuvaxovid XBB.1.5 (Novavax) COVID-19 vaccines boxes have been decommissioned by the NCCS.

4.3 Shelf-Life

- 4.3.1 Expiry date:

Expiry date is stated on the vial label and the carton. Do not use the vaccine after the expiry date.

- 4.3.2 Discard date and time

The discard date and time must be written on the vial once the vial is initially punctured. This is calculated by adding **6 hours** to the time of the initial puncture and this time and date must be recorded on the vial. The vaccine can be stored between +2°C to +25°C during this 6 hour period.

From a microbiological point of view, after first opening (first needle puncture), the vaccine should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.

4.4 Storage

Unopened vial

- Store in a refrigerator (+2°C to +8°C).

- Do not freeze.
- Keep the vials in their original outer carton in order to protect from light.

An unopened vial can be stored at +2°C to +8°C, protected from light, within the product shelf life stated on the vial label and the carton.

Unopened Nuvaxovid XBB.1.5 vaccine has been shown to be stable for up to 12 hours at + 25°C. Storage at + 25°C is not the recommended storage condition but may guide decisions for use in case of **temporary temperature excursions** during the storage at +2°C to +8°C.

Punctured vial

Chemical and physical in-use stability has been demonstrated for 6 hours at room temperature (maximum +25°C) from the time of first needle puncture to administration.

4.5 Presentation and Preparation

Nuvaxovid XBB.1.5 is presented as a multi-dose vial containing 2.5 ml of dispersion in each vial (type I glass) with a stopper (bromobutyl rubber) and an aluminium overseal with blue plastic flip-off cap. . Each carton of Nuvaxovid XBB.1.5 contains two multi-dose vials

Preparation for use

- The vaccine comes ready to use.
- Unopened vaccine should be stored at +2°C to +8°C and kept within the outer carton to protect from light.
- Immediately prior to use, remove the vaccine vial from the carton in the refrigerator.
- Each multi-dose vial contains a colourless to slightly yellow, clear to mildly opalescent dispersion free from visible particles.
- Visually inspect the contents of the vial for visible particulate matter and/or discolouration prior to administration. Do not administer the vaccine if either are present.
- Record the discard date and time on the vial label. The discard time is 6 hours after first puncture when stored at room temperature (maximum +25°C).
- Gently swirl the multi-dose vial before and in between each dose withdrawal. Do not shake.

Administer the vaccine

- An overfill is included per vial to ensure that a maximum of 5 doses (vial of 2.5 ml) of 0.5 ml each can be extracted.

- Each 0.5 ml dose is withdrawn into a sterile needle and sterile syringe to be administered by intramuscular injection, preferably in the deltoid muscle of the upper arm.
- Do not mix the vaccine in the same syringe with any other vaccines or medicinal products.
- Do not pool excess vaccine from multiple vials.

5. Consumables, Patient Information Leaflets (PILs), Record Cards and Other Equipment

A national distribution service will provide all necessary supplies to handle, prepare and administer the vaccine, including PPE and critical clinical and non-clinical consumables. These are not included in this SOP.

Other equipment includes:

Anaphylaxis Kits: Refer to National Immunisation Advisory Committee Guidelines.

<https://www.hse.ie/eng/health/immunisation/hcpinfo/schoolproghcp/protocols/anaphylaxis2016.pdf>

The adrenaline will be provided by a pre-determined community/ hospital pharmacy as agreed at a local level.

Storage Equipment: A pharmaceutical fridge must be used to store vaccines. The fridge should be set to maintain the temperature at $+5^{\circ}\text{C} \pm 3^{\circ}\text{C}$, and alarms should take into account the need to maintain the temperature above $+2^{\circ}\text{C}$ and less than $+8^{\circ}\text{C}$.

Fridges should be validated and monitored in accordance with existing local procedures.

6. Stock Control, Security and Monitoring of Wastage

A physical stock count of COVID-19 vaccine vials should be completed and it should match the stock count recorded on the IT system.

Sites will need to ensure that vaccines are stored securely at all points between receipt and use or disposal.

All waste must be handled in such a way as to prevent theft and /or misuse, both on site and after removal from the site.

Unopened vials (in original cartons) must be returned to NCCS for destruction following the routine protocol for all expired /damaged vaccines.

Dispose empty or partial empty vials into sharps bins safely as per health care management policy.

Dispose syringes and needles into sharps bins according to normal local waste management procedures.

Original cartons must be defaced using permanent black marker pens, and placed into appropriate waste sack for incineration, as soon as possible after they become empty.

7. Health and Safety

There are no special requirements for routine handling and dealing with spillages of Nuvaxovid XBB.1.5 COVID-19 vaccine.

Health and safety risk assessments should be undertaken locally to ensure these risks are adequately controlled.

APPENDIX C: ADVICE FROM THE NATIONAL IMMUNISATION ADVISORY COMMITTEE REGARDING FEVER AFTER COVID-19 VACCINATION THE NATIONAL IMMUNISATION ADVISORY VACCINATION



National Immunisation Advisory Committee

29 December 2020

Statement on fever following COVID-19 vaccination

Clinical judgement should be used based on the individual case. Carers and patients should be advised that if they have any concerns, they should seek advice from their GP.

Post immunisation fever

Vaccinated individuals should be advised that COVID-19 vaccines may cause a mild fever which usually resolves within 48 hours. This is a common, expected reaction. Isolation and further investigation are not generally required.

Fever may be managed symptomatically with an antipyretic, provided there are no other concerns.